OFFICE OF THE CHIEF ECONOMIST

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Diagnosing COVID-19

A perspective from U.S. patenting activity

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A perspective from U.S. patenting activity

Project team:

This analysis was prepared by the United States Patent and Trademark Office's Office of the Chief Economist, in collaboration with the USPTO's Patents Business Unit and the Office of Policy and International Affairs.

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Key findings

- The number of COVID-19 diagnostic patent filings that were published by the USPTO surged and then receded in the months following the emergence of the coronavirus—such publications peaked in the fourth quarter of 2021, which generally reflects applications filed in April, May, and June of 2020.

- COVID-19 diagnostic filings make up about 30% of all COVID-19 public patent filings, hovering at about one out of every three COVID-19 filings at the USPTO.

- Small companies and universities led the way in COVID-19 diagnostic public patent filings at the USPTO with the top filer being a diagnostic startup company.

- U.S. government financial support helped spur COVID-19 diagnostic inventions, as indicated by government interest statements contained in the filings. About 10.7% of all COVID-19 public patent filings show government support, with the National Institutes of Health leading other agencies.

- U.S.-based applicants are leading those from other countries in U.S. COVID-19 diagnostic public patent filings, making up most of the volume, including most of the top 21 applicants.

- COVID-19 diagnostic public patent filings are concentrated in a few technologies such as analyzing materials and measuring enzymes, nucleic acids, and microorganisms.

- Many applications for inventions directed at COVID-19 diagnostics also disclose methods of treatment (about 8.6%). For instance, inventions for antibodies may diagnose and treat COVID-19.

- Among 5,585 global COVID-19 diagnostic patent families found in this study, 47% have at least one filing at the China National Intellectual Property Administration (CNIPA), the most of any jurisdiction.

I. Introduction

The SARS-CoV-2 virus, and the disease it causes (COVID-19), created a public health crisis that strained health care systems and sparked an unprecedented innovation race to find new vaccines, therapeutics, and diagnostics. At stake were millions of lives across the globe. Looking back from 2023, the innovation response to the crisis has been truly impressive. New vaccines and therapeutics have lowered morbidity and greatly reduced mortality from COVID-19. Innovations in diagnostics allowed for the identification of infected persons outside of health care facilities, enabled disease tracking, and informed preemptive policy responses using the latest epidemiologic data.[1] At present, the U.S. Food and Drug Administration (FDA) lists 34 over-the-counter at-home COVID-19 test kits.[2]

This study is part of an emerging body of work that seeks to understand the workings of the innovation system in times of crisis. It builds on existing work by the World Intellectual Property Organization (WIPO). In March 2022, WIPO released a global patent analysis of inventions related to COVID-19, particularly vaccines and therapeutics (WIPO 2022). Later in July 2022, the Centre for Economic Policy Research (CEPR) released an edited volume analyzing how the COVID-19 crisis shaped the innovation landscape of the world's major economies. Based on contributions from intellectual property (IP) offices and scholars from around the world, the editors concluded that innovation systems were surprisingly resilient and responsive (Fink et al. 2022).[3] Most recently, in April 2023, WIPO released an update of its COVID-19 vaccine and therapeutics report (WIPO 2023a).[4]

These reports, however, do not specifically examine innovation in COVID-19 related diagnostics. This study starts to fill that gap by focusing on U.S. patenting activity to gauge the extent and nature of innovation related to the diagnosis of COVID-19. In general, patent documents provide insights into how scientific discoveries enable technological inventions that subsequently become products and services. These insights make a patenting perspective valuable for identifying who is inventing, the nature of invention, and where those inventions are happening.

1. Information about COVID-19 testing, treatments, and medications is available from the Centers for Disease Control and Prevention (CDC) at www.cdc.gov/coronavirus/2019-ncov/index.html.

2. See "At-Home OTC COVID-19 Diagnostic Tests" at www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests.

3. Available from cepr.org/publications/books-and-reports/resilience-and-ingenuity-global-innovation-responses-covid-19.

4. Available from www.wipo.int/edocs/pubdocs/en/wipo-pub-1075-23-en-covid-19-vaccines-and-therapeutics.pdf.

II. Identifying COVID-19 diagnostic patent filings

This section provides an overview of the approach we used to identify public patent filings that relate to COVID-19 diagnostics. At a broad level, we follow a traditional approach that finds relevant patent documents using keyword and classification queries (Toole et al. 2020). A similar approach was used for the WIPO studies of COVID-19 vaccines and therapeutics (WIPO 2022, 2023a).

As a working definition, a COVID-19 diagnostic public patent filing is any published patent application (i.e., pre-grant publication or PGPub) or issued patent that facilitates the detection and identification of the SARS-CoV-2 virus. This definition is consistent with the definition of diagnosis from the National Library of Medicine's Medical Subject Heading (MeSH) ontology, which states that diagnosis is "the determination of the nature of a disease or condition, or the distinguishing of one disease or condition from another."[5] We also adopt the MeSH definition of COVID-19, which describes symptoms like fever and loss of taste or smell, and states that COVID-19 is caused by the coronavirus SARS-CoV-2.[6]

Similar to WIPO, we follow a three-step approach: (1) identify an expansive group of published patent applications and issued patents that relate to COVID-19; (2) search within that group to identify the subset that relates to COVID-19 diagnostics; and (3) perform manual evaluation to determine search performance. Given the complexity of the linkages between patent filings and COVID-19, we performed this sequence of steps twice to learn about the performance of the procedure. First, we created a narrow *COVID-19 specific* grouping, and then we subsequently broadened the search criteria to create a *COVID-19 related* grouping:

1. COVID-19 specific: To create the set of COVID-19 specific patent documents, we looked for keywords in Derwent titles and abstracts, which are manually created by Clarivate and available in their Derwent Innovation and Derwent World Patent Index (DWPI) patent data products. Derwent creates these summaries to enhance patent search.[7] This query returned 9,094 public patent documents from across the world (see the appendix for further details).
2. COVID-19 related: We identified COVID-19 related patent documents by searching for keywords in the **full text** of patent documents, including all parts such as the detailed description. This set includes diverse examples of COVID-19 related patent filings. For example, one U.S. patent application is titled "Board Game Relating to the COVID-19 Pandemic" (U.S. Publication No. 2021/0387081 A1). It also contains patent documents that are only peripherally related to COVID-19 (e.g., if the description describes the invention's use for many viruses and diseases, with COVID-19 discussed as one example). This query strategy returned 18,540 public patent documents from across the world, almost twice as many as the COVID-19 specific approach.

5. The MeSH definition for diagnosis continues, "assessment may be made through physical examination, laboratory tests, or the likes. Computerized programs may be used to enhance the decision-making process." See www.ncbi.nlm.nih.gov/mesh/68003933.

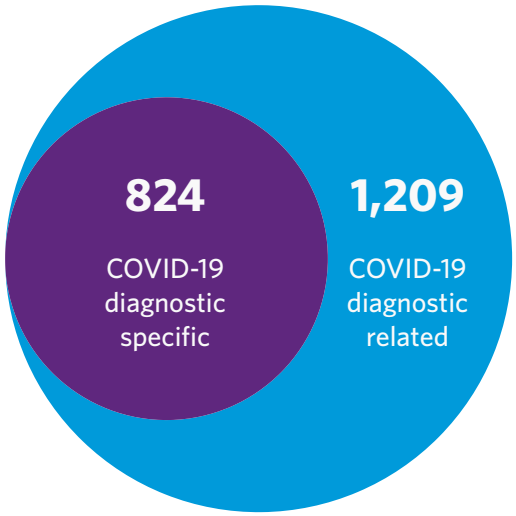
6. See www.ncbi.nlm.nih.gov/mesh/2052179.

7. See www.clarivate.com/products/ip-intelligence/patent-intelligence-software/derwent-innovation.

We identified diagnostics within the COVID-19 specific and related groups by selecting only those patent documents that were classified in several DWPI categories covering diagnostics (e.g., B12K containing diagnostics for respiratory viruses and diseases). The U.S. document counts for COVID-19 diagnostic public patent filings are shown in Figure 1. As expected, all of the diagnostic filings from the specific query group are also contained in the related query group, but the latter is larger. The COVID-19 diagnostic-specific set includes 824 public patent filings at the USPTO while the related set has 1,209.

We evaluated the COVID-19 diagnostic-specific and diagnostic-related queries using two approaches. The first assessed precision, or the likelihood that a given patent document retrieved by the query is actually a COVID-19 diagnostic. Several supervisory patent examiners with extensive experience in this technology area annotated a random sample of the U.S. documents to determine which were reasonably classified as COVID-19 diagnostic patent filings. Of the patent documents labeled as COVID-19 diagnostic-specific, 67.5% were actually COVID-19 diagnostics, whereas only 46.2% of the COVID-19 diagnostic-related documents were. This finding demonstrates that expanding the search approach to include all application parts, rather than just the information summarized by Derwent, significantly reduces the likelihood that any given document returned by the query is actually a COVID-19 diagnostic.

Figure 1. USPTO public patent filing counts for the specific and related query approaches, December 2019–April 2023



Our second evaluation assessed recall, or the likelihood that a given COVID-19 diagnostic is returned by the query. While we don't have a gold standard of patent documents known to be COVID-19 diagnostics, we do have a set of applications that were granted participation in the USPTO's COVID-19 Track 1 program (which accelerated patent examination for COVID-19 applications).[8] Of the patent documents in the Track 1 program, 86% were in the COVID-19 related query (based on COVID-19 keywords, and not limited to diagnostics) and 53.7% were in the COVID-19 specific query. These results highlight a tradeoff between precision (discussed above) and recall—the likelihood of finding documents that actually are relevant to COVID-19. Expanding the set of COVID-19 documents using the full text of the patent document increased recall but reduced precision. Researchers must choose the appropriate balance.[9]

8. See www.uspto.gov/initiatives/covid-19-prioritized-examination-pilot.

9. More information about our evaluation is available in the appendix.

III. Findings

The findings presented below are based on COVID-19 diagnostic published patent filings that were found using the COVID-19 specific search strategy. Every finding discussed, except for the one on international patent families, describes public filings made at the USPTO.

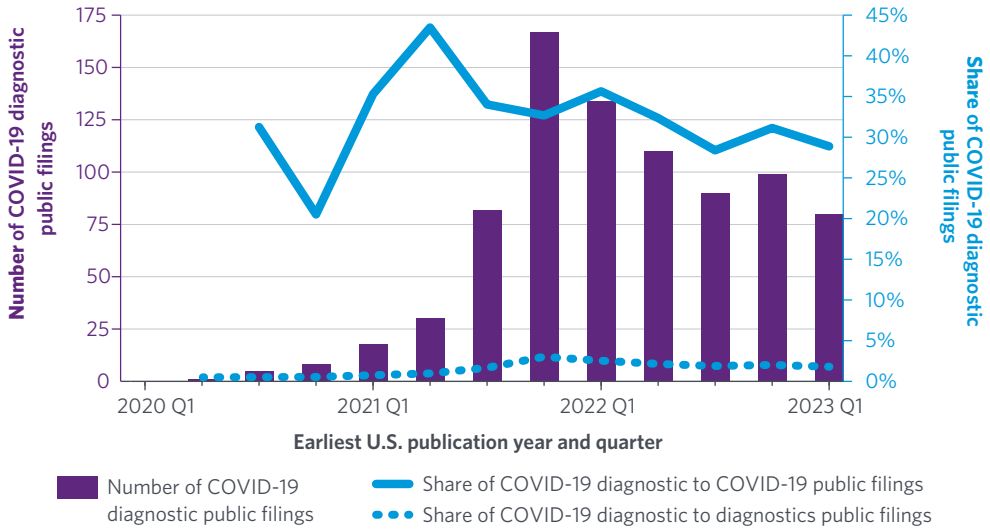
A. U.S. COVID-19 diagnostic patent filings surged

The number of COVID-19 diagnostic patent filings published at the USPTO surged in the months following the emergence of the coronavirus. Figure 2 illustrates this surge using public information on pending U.S. patent applications (which are typically published 18 months after the filing date) and public information on granted U.S. patents (which can be issued within a few months of the filing date when an accelerated examination program is used).[10] The surge (represented by the solid bars) has a distinctive wavelike shape that peaks in the fourth quarter of 2021—generally corresponding to application filing dates in April, May, and June of 2020. In the beginning of 2021, 18 filings became public, and this number peaked at 167 in the last quarter of 2021, an 828% increase. The peak quarter alone had 20% of all the published patent filings found by the COVID-19 diagnostics-specific search used for this study.

Although the surge receded to 80 new published patent filings by the first quarter of 2023, the current share of COVID-19 diagnostics among all COVID-19 associated patent filings at the USPTO has remained fairly stable at about 30% (one out of every three, as shown by the solid line in Figure 2). This trend is consistent with the WIPO report that found a surge and subsequent tapering-off pattern for overall COVID-19 patenting activity as well as for therapeutic and vaccine-related patent filings (WIPO 2023a). Nevertheless, in the broader context, COVID-19 diagnostic public patent filings are a small share of overall diagnostic public patent filings at the USPTO (the dashed line in Figure 2). The COVID-19 share was about 2.6% at its peak and represents about 1.4% in the most recent data (2023 Q1).

10. Abandoned applications are also included if the applications were published as PGPubs.

Figure 2. Volume and share of U.S. COVID-19 diagnostic public patent filings, 2020 Q1–2023 Q1



Notes: A public filing is defined as a patent application evidenced by a granted U.S. patent or by a published PGPub; hence, it is based on granted patents and pending/non-granted applications with PGPubs. The "Earliest U.S. publication year and quarter" uses the PGPub publication date for granted patents having a PGPub; otherwise, it uses the publication date of the granted patent or of the PGPub not having a granted patent.

B. Small companies and universities led the way in U.S. COVID-19 diagnostic patent filings

With the onset of the global pandemic in early March 2020, policymakers in the U.S. and abroad moved quickly to impose protective measures and to authorize funds directed toward the development of vaccines, therapeutics, and diagnostics.[11] The call to action was broad and touched every group in the innovation system—private sector companies, universities and nonprofits, government agencies, and individuals.

Our analysis reveals that companies accounted for the largest share of U.S. COVID-19 diagnostic public filings between December 1, 2019, and April, 2023. Out of the 824 public filings observed in this period, companies were responsible for just over 58% (Figure 3). Universities, nongovernment research institutes, and hospitals had 220 filings (or about 27% of the total). Perhaps surprisingly, individuals with no observable affiliation to a laboratory, research facility, or other scientific infrastructure accounted for 109 (or 13%) of total public

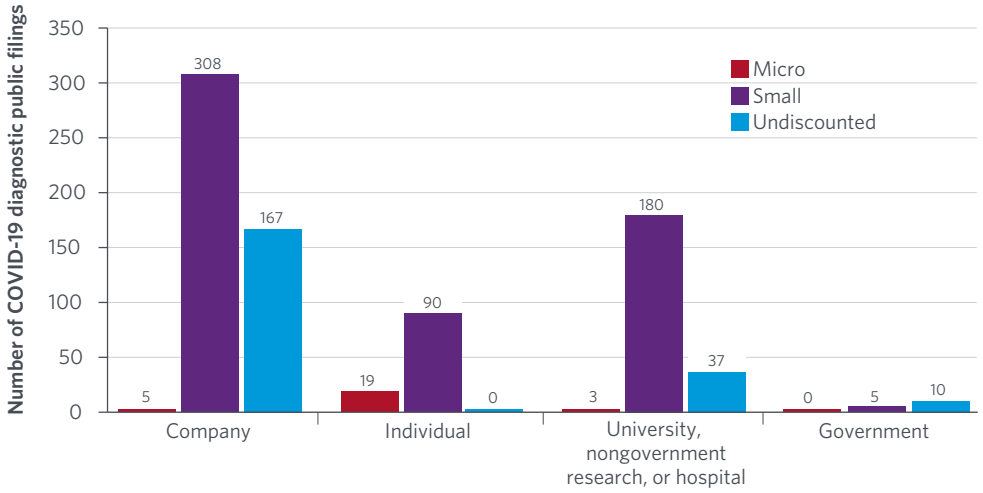
11. A variety of sources lay out the particular restrictions and policies adopted around the world. For instance, see the International Monetary Fund (IMF), "Policy Responses to COVID-19" (www.imf.org/en/Topics/imf-and-covid19/Policy-Responses-to-COVID-19), and the Organization for Economic Cooperation and Development (OECD), "Key Policy Response from the OECD" (www.oecd.org/coronavirus/en/policy-responses).

filings.[12] Governments were named on only a handful of patent filings through April 2023. However, as we further discuss below, the federal government funded a significant amount of research leading to patent filings and thus retained certain rights.

Although most characteristics of these filers are not available for analysis, the USPTO has a tiered patent fee schedule that provides discounts for certain organizations and individuals. The first category is called undiscounted and typically covers organizations with 500 or more employees. Fee discounts are available to those who satisfy the criteria for a small entity. Importantly, universities, research institutes, and nonprofits in the U.S. and abroad qualify for small entity status regardless of size. Within the group of small entities, a further micro entity discount may be available.[13]

Looking at the volume of U.S. COVID-19 diagnostic public filings by entity size shows that nearly 71% were associated with small entities (Figure 3). Among companies, about 64% of the COVID-19 diagnostic filings were by small entities. For universities, nongovernment research institutes, and hospitals, nearly 82% were small entities. The volume of filings by small entities was larger than that of undiscounted and micro entities in every applicant group except government. This finding may not be surprising for universities and nongovernment research institutes, but it stands out prominently among companies. It contrasts with the fact that most of the patent applications received and patents issued by the USPTO are to undiscounted entities. For instance, less than 24% of all U.S. patents issued in 2022 went to small and micro entities.[14]

Figure 3. U.S. COVID-19 diagnostic patent filings by applicant entity type and size, December 2019–April 2023



Although the number of public patent filings assigned to U.S. government agencies was relatively small (15 of the 824 documents identified), this number understates the contribution of federally sponsored research to new COVID-19 diagnostics. Under the Bayh-Dole Act of

12. The circumstances under which these inventions were developed are not known, and these public filings need more investigation to better understand the nature of the inventions claimed.

13. More information on the requirements to claim small and micro entity status is available at www.uspto.gov/patents/apply/save-on-fees.

14. See USPTO annual reports at www.uspto.gov/about-us/performance-and-planning/uspto-annual-reports.

1980, patent applications from nongovernmental organizations that resulted from federal sponsorship must include a government interest statement (Manual of Patenting Examination Procedure [MPEP] § 310).[15] These statements are included in PatentsView, a patent data visualization and analysis platform. PatentsView identifies and parses the government interest statements and makes the resulting information available to the public.[16]

Table 1 provides a summary of the COVID-19 diagnostic public filings that contain a government interest statement. Overall, 88 out of the 824 have government interest (10.7%). Small and micro entities make up about 81% of these. Among the sponsoring agencies, the National Institutes of Health (NIH) within the Department of Health and Human Services (HHS) leads with 57 public filings, three-quarters of which are filed by small entities. Second is the National Science Foundation (NSF), with the Department of Defense (DOD) having the third highest volume.

Table 1. Federally supported COVID-19 diagnostic public patent filings, December 2019–April 2023

Government interest (GI) statements	Applicant entity type			
	Micro	Small	Undiscounted	**Total**
Number of COVID-19 public filings with GI	2	69	17	**88**
Number by federal department or agency				
Department of Defense (DOD)	-	3	10	**13**
Department of Energy (DOE)	-	-	1	**1**
Department of Health and Human Services (HHS)	1	45	11	**57**
Department of Justice (DOJ)	-	1	-	**1**
National Science Foundation (NSF)	1	18	-	**19**
Other United States government	-	5	-	**5**

Another way to learn more about who is filing U.S. COVID-19 diagnostic patent applications is to look at the names of the top filers. Figure 4 lists the top 21 organizations (no individuals made the top 21). The most striking result is the dominance of U.S.-based companies and research institutions among the top filers in the United States: 17 of the top 21. This result contrasts sharply with the findings presented by WIPO on global top filers in COVID-19 vaccines and therapeutics (WIPO 2023a). WIPO shows only one U.S.-based entity among the top 16 in therapeutics and two in the top 16 for vaccines (see Tables 4 and 5 in WIPO 2023a).[17]

15. See also Bayh-Dole Act (Pub. L. 96-517).

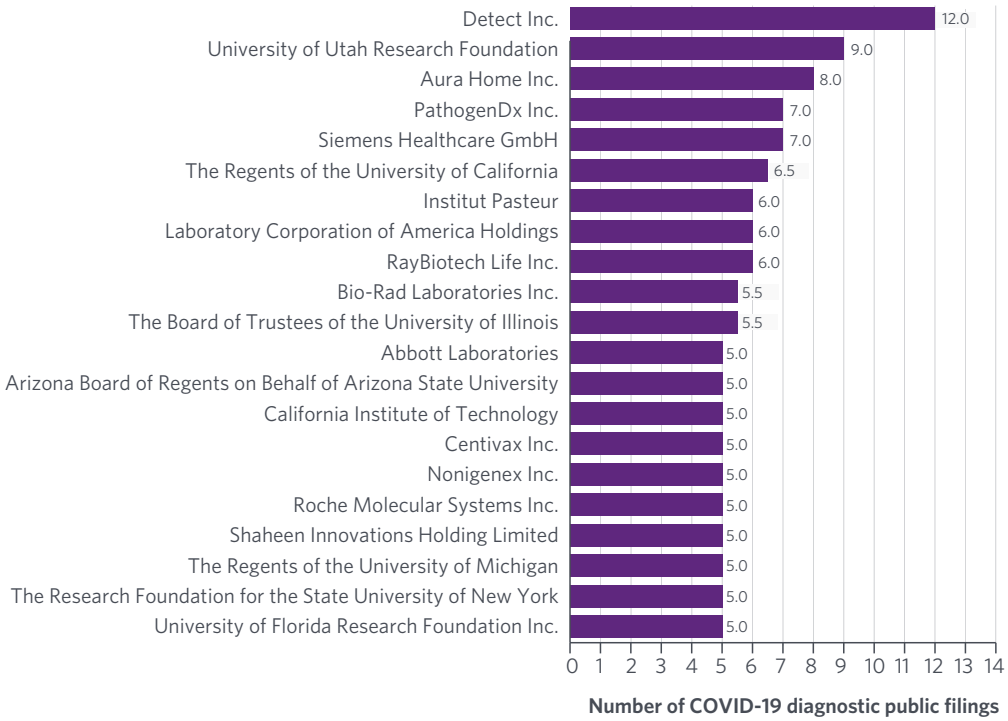
16. See PatentsView's bulk download section to access the data, available under "Datasets" at www.patentsview.org/.

17. The WIPO lists, and the list shown in Figure 4 in this report, only have two entities in common: Institut Pasteur and the Regents of The University of California.

At least in part, this difference reflects WIPO's focus on international patent families and the substantial volume of COVID-19 therapeutic and vaccine filings in China, while our study is more narrowly focused on individual COVID-19 diagnostic public filings in the U.S.

At this time, the top applicant for U.S. COVID-19 diagnostics is Detect Inc. with 12 public filings (Figure 4). Detect Inc. is a young venture capital-backed startup company founded in March 2020 by an accomplished researcher and entrepreneur, Jonathan M. Rothberg. While Detect Inc. originally received an FDA Emergency Use Authorization (EUA) for its COVID-19 diagnostic test, the EUA was revoked (at the request of Detect Inc.) in April 2023, a case that demonstrates some of the challenges associated with bringing new technologies to market during times of crisis.[18] The second company on the list is Aura Home Inc., which is also a venture capital-backed company founded in 2015 by former employees of Twitter. Aura Home Inc. started with a focus on digital frames and photo sharing apps and has expanded to COVID-19 diagnostics. For example, U.S. Patent No. 11,350,889 B2 is titled "COVID-19 Risk and Illness Assessment Method."[19] The fourth ranked applicant is another small company, PathogenDx Inc., that developed a COVID-19 test called DetectX-Rv that received an FDA EUA in July 2021.[20]

Figure 4. Top filers of U.S. COVID-19 diagnostic public patent filings, December 2019–April 2023



Notes: Diagnostic public patent filings are allocated to their organizations on a fractionalized basis. For example, if one filing is associated with two organizations, then each organization would receive 0.5 filings.

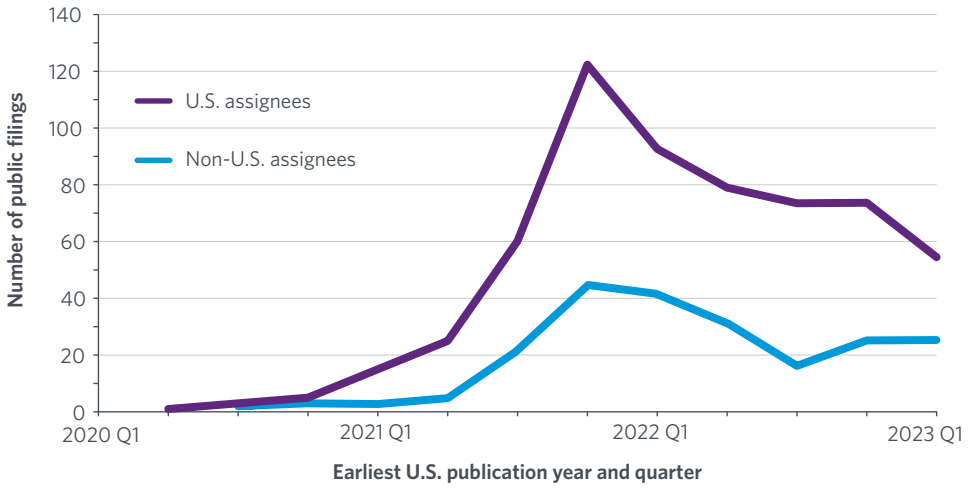
18. See letter from Jeffrey E. Shuren, April 14, 2023, available from www.fda.gov/media/167181/download.

19. The invention does not diagnose, per se, but it does allow one to determine risk of exposure.

20. See letter from Denise M. Hinton, July 22, 2021, available from www.fda.gov/media/147800/download.

The finding that U.S.-based applicants are leading in U.S. COVID-19 diagnostic patent filings is generally true (that is, beyond the top 21 filers). Figure 5 reproduces Figure 1 but breaks out the overall trend into U.S.-based and non-U.S. based applicants. To date, U.S. applicants always have more U.S. public filings over the time period of 2020 Q1 through 2023 Q1. At the peak of the COVID-19 diagnostic filing wave (2021 Q4), U.S.-based applicants accounted for 121 U.S. public filings, or 72%. It is notable, however, that international patent applications filed with WIPO under the Patent Cooperation Treaty (PCT) have up to 30 months before entering the national phase (that is, filing with a national IP office). This timeline means that non-U.S. based application filings with the USPTO may increase in the coming quarters.

Figure 5. Number of COVID-19 diagnostic public patent filings, 2020 Q1–2023 Q1



C. U.S. COVID-19 diagnostic patent filings are concentrated in a handful of technologies

Diagnosing COVID-19—detecting and identifying its presence—can be accomplished using a wide variety of scientific methods. For instance, one might screen and identify COVID-19 using laboratory tests, antigens, viral nucleic acids, immunological molecules, pathological changes in organs, and so forth (Abdelhamid and Badr 2021). This myriad of potential scientific approaches is further multiplied by the possible role that digital, mechanical, or other technologies might play in enhancing, complementing, or otherwise making a diagnostic approach useful and desirable for physicians and patients. Although these complex combinations of science and technology are not easy to summarize, the Cooperative Patent Classification (CPC) system offers a useful framework by placing patent documents into a hierarchical schema with different degrees of granularity. A patent document usually has more than one assigned CPC code within the schema, and we utilize all assigned U.S. codes at the subclass level.[21]

21. For more information, see the joint European Patent Office (EPO) and USPTO webpage for the CPC system at www.cooperativepatentclassification.org/home.

Figure 6. Top 10 CPC subclasses of U.S. COVID-19 diagnostic public patent filings, December 2019–April 2023

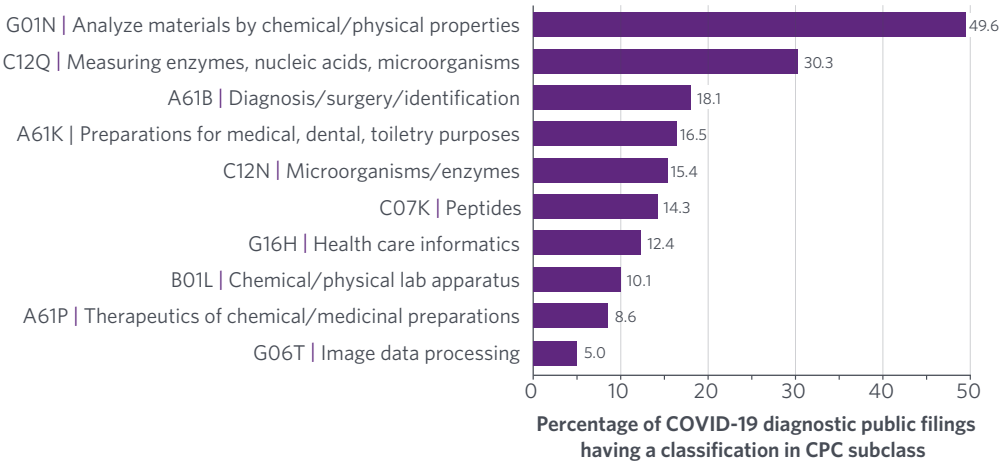
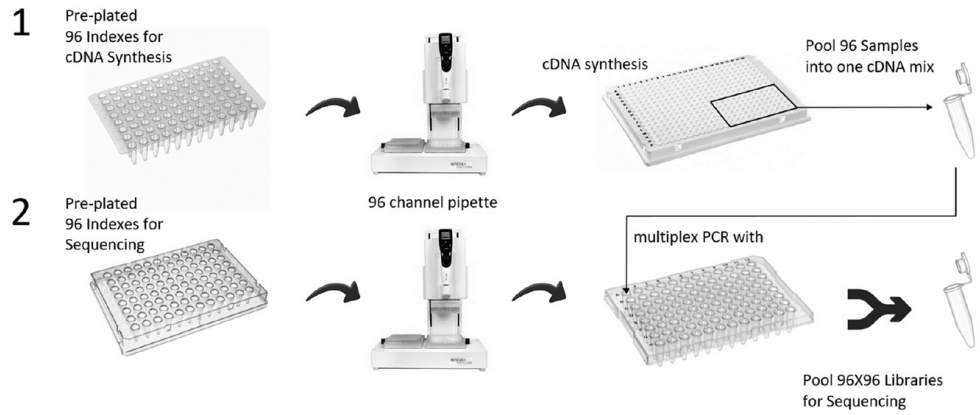


Figure 6 shows the top 10 CPC subclasses that contain COVID-19 diagnostic public filings at the USPTO. Looking at only 10 subclasses (out of over 2,000 in CPC) already shows a relatively quick drop off in the concentration of CPC codes assigned to COVID-19 diagnostic documents from nearly 50% in the top subclass to 5% in the tenth. The two most common subclasses focus on analyzing and measuring: G01N captures inventions "investigating or analyzing materials by determining their chemical or physical properties," and C12Q captures inventions "measuring or testing processes involving enzymes, nucleic acids or microorganisms" (see Example 1). Perhaps the most interesting among the top 10 subclasses is G16H ("health care informatics"), as it reflects, at least in part, the in-home testing needs that grew dramatically with the emergence of COVID-19 (see Example 2).

Example 1: COVID-19 diagnostics patent in CPC subclass C12Q for "measuring enzymes, nucleic acids, and microorganisms"

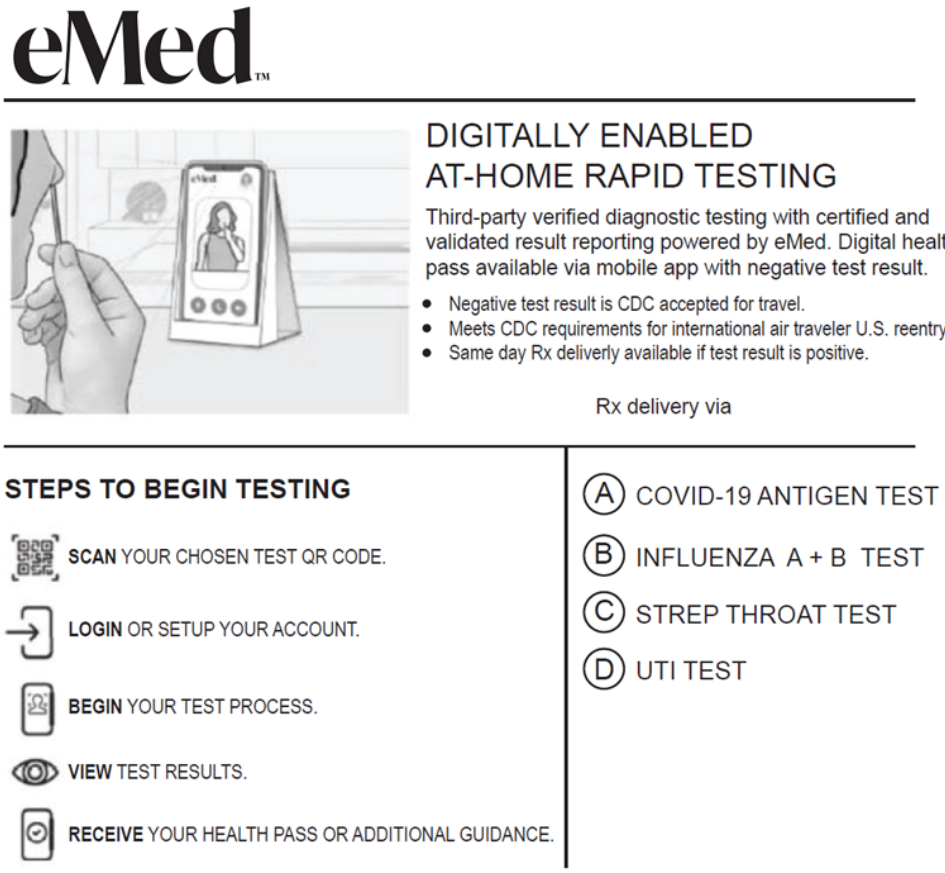


High-throughput detection of pathogen RNA in clinical specimens

U.S. Patent No. 10,941,453 B1, to Paragon Genomics Inc. in Hayward, California, U.S., was granted for a high-throughput diagnostic assay involving an array of wells in an automatic liquid handler. The system increases speed and reduces cost by testing many patient samples simultaneously.

Importantly, Figure 6 shows that inventions directed to COVID-19 diagnostics are not always separate and distinct from inventions for COVID-19 vaccines and therapeutics. For instance, 8.6% of all the U.S. COVID-19 diagnostic public filings fall into CPC subclass A61P ("specific therapeutic activity of chemical compounds or medicinal preparations"). Many of these inventions are for antibodies that can be used to both diagnose and treat COVID-19 (see Example 3).

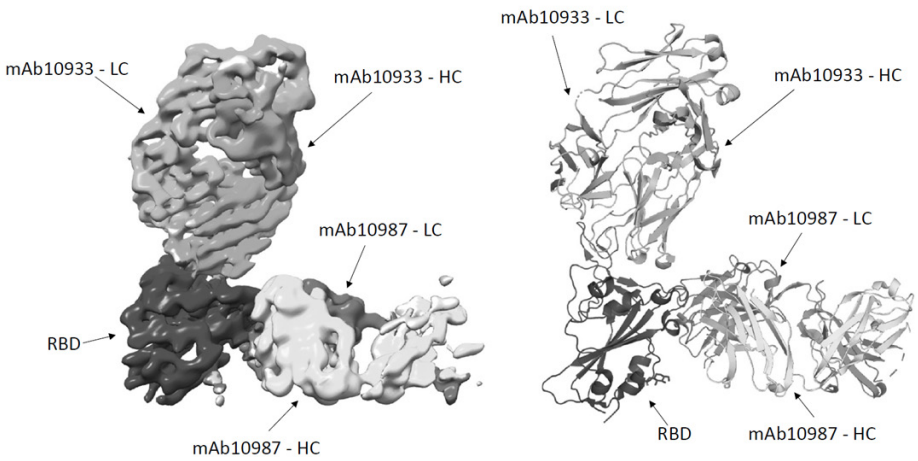
Example 2: COVID-19 diagnostics patent in CPC subclass G16H for "health care informatics"



Systems, devices, and methods for diagnostic aid kit apparatus

U.S. Patent No. 11,369,454 B1, to eMed Labs LLC in Miami, Florida, U.S., was granted for a portable device using augmented reality for remote diagnosis that is connected to a cloud-based health care informatics system. The system offers a user-friendly approach to simplify the steps of at-home testing, coordinating with pharmacies, and reordering diagnostic supplies.

Example 3: COVID-19 diagnostics patent in CPC subclass C07K for "peptides"



Anti-SARS-CoV-2-spike glycoprotein antibodies and antigen-binding fragments

U.S. Patent No. 10,787,501 B1, to Regeneron Pharmaceuticals Inc. in Tarrytown, New York, U.S., was granted for antibodies that bind to spike proteins on the surface of SARS-CoV-2. The inventors envisioned the antibodies to be used as either a component of a therapeutic or a diagnostic device.

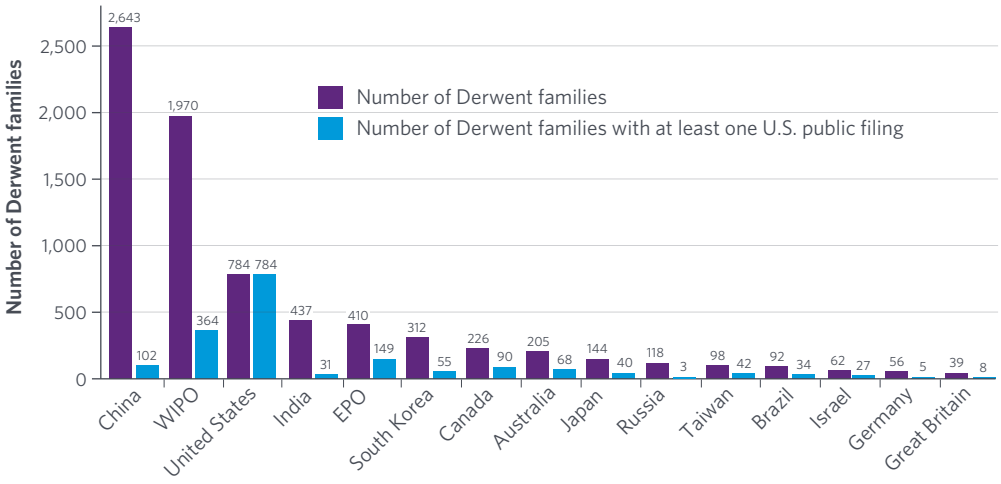
D. The China National Intellectual Property Administration (CNIPA) has 47% of all global COVID-19 diagnostics patent families

Looking globally, CNIPA leads all IP offices for COVID-19 diagnostic public patent filings based on counts of Derwent patent families. Patent families are groups of one or more patent documents that help to avoid overcounting of similar inventions, particularly when filings are observed by the same filer across multiple jurisdictions.[22] CNIPA had 2,643 COVID-19 diagnostic patent families (left bar for each IP organization in Figure 6) as of 2023 Q1, which is about 47% of all 5,585 Derwent families identified through the COVID-19 specific query. The presence of U.S. patent filings in COVID-19 diagnostic patent families having a CNIPA filing is quite low at only 102 out of 2,643, about 3.9% (right bar for each IP organization in Figure 6). The national IP office with the second largest number of Derwent patent families is the USPTO with 784. While China leads in the number of Derwent patent families, these inventions are generally not patented abroad, with other countries internally developing their own diagnostics.

22. See the appendix for more details on Derwent patent families.

WIPO had 1,970 COVID-19 diagnostic Derwent patent families, or about 35% of the total number found in this study. These patent families reflect international patent applications filed under the PCT. The PCT route allows applicants to specify any of the national or regional patent offices from the 157 contracting states, called the national phase of the PCT process.[23] Because the national phase typically begins 30 months from the international filing date, it is unclear at this time in which jurisdictions applicants will eventually choose to file. We do know that currently families with a U.S. public filing make up about 18%, or 364, of the WIPO families.

Figure 7. Counts of global Derwent patent families by IP organization, December 2019–April 2023



23. More information on the national phase is available at "PCT Applicant's Guide Introduction to the National Phase" (pctlegal.wipo.int/eGuide/view-doc.xhtml?doc-code=PCTNP&doc-lang=en&doc-type=guide). Also, a list of PCT contracting states may be found at www.wipo.int/pct/en/pct_contracting_states.html.

IV. Discussion and limitations

National innovation systems were surprisingly responsive to the urgent needs created by the COVID-19 pandemic (Fink et al. 2022). The rapid introduction of COVID-19 diagnostics shortly after the onset of the pandemic allowed individuals to better monitor their health, and it provided policymakers with crucial information needed to manage the public health crisis. Our study reveals that small companies and universities led the way in developing inventions to diagnose COVID-19, as evidenced by public U.S. patent filings through April 2023. Those organizations were also more likely to use government support, especially from the NIH and NSF.

It is important to note that the results found in this study, as in any patent landscape study, depend critically on the definitions used, how those definitions are implemented in the queries, and the coverage of the queried data source. Our analysis revealed that public patent filings for COVID-19 diagnostics are not fully distinct and separate from those for COVID-19 related vaccines and therapeutics. We observed that public patent filings involving antibodies and antigens often disclose diagnostic applications of the invention as well as other potential virus disease targets beyond COVID-19. Relatedly, some platform product inventions may have multiple uses beyond diagnosing COVID-19, and they are part of a larger class of diagnostics covering multiple conditions.

Finally, linking patented inventions to commercialized products is very difficult, even though in some cases patents are listed on product packaging and company websites (a legal procedure called patent marking).[24] We were able to find some information regarding a few of the COVID-19 diagnostic tests with an FDA EUA in the U.S.[25] However, we were unable to identify the patents covering tests with an EUA in a vast majority of the cases. The limited information we could find revealed that there wasn't one strategy that companies and organizations used to successfully develop COVID-19 diagnostic tests. Companies were potentially able to reconfigure existing diagnostic testing systems to diagnose COVID-19, as well as develop entirely new testing platforms.

24. See 35 U.S.C. 287, as cited in MPEP, Appendix L, at www.uspto.gov/web/offices/pac/mpep/mpep-9015-appx-l.htm-l#d0e305958.

25. See FDA, "Emergency Use Authorization," at www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulato-ry-and-policy-framework/emergency-use-authorization.

Appendix: Approach for identifying COVID-19 patenting and diagnostics

I. Search approach

Our landscaping approach consists of two search queries: one that identifies COVID-19 specific patent documents, and one that focuses on documents that are related to COVID-19. Both queries rely on a set of terms that correspond to COVID-19, but they differ in which sections of the patent documents are searched. The specific query looks for the terms in Derwent information (like Derwent titles and abstracts), while the related query expands the search to the full text of patent documents.[26] Derwent titles and summaries are produced by Clarivate and are useful for conducting patent searches. Patent documents with terms that correspond to COVID-19 within Derwent titles and summaries are more likely to indicate that the inventions focus explicitly on COVID-19. Alternatively, finding terms that correspond to COVID-19 anywhere throughout the patent document may simply indicate that the invention peripherally relates to COVID-19; for example, if the term is used in one enablement (among many) in the description of the invention.

Table A1 contains the keywords used to identify COVID-19 patent documents.[27] The keywords are provided in the first column, with their descriptions in the second column. For example, the keyword "*10covid19*10" is used to identify patent documents that contain "covid19". Other keywords identify documents that contain "sars-cov-2", "novel coronavirus," and "2019 coronavirus."

After identifying a set of documents using both the COVID-19 specific and related approaches, the sets are narrowed to diagnostics by selecting those in several Derwent World Patents Index (DWPI) categories. Table A2 contains the set of DWPI classifications used, which includes "A12-V03C2" for "Testing, diagnosis, pathology" and "B12-K*" for "Diagnostics, respiratory active type," among others.

Our approach extracts all patent documents within each Derwent patent family that contains at least one document that satisfies the queries (Derwent families are collections of documents meant to cover a single invention).[28] For example, if the query identifies a U.S. PGPub, then the U.S. patent will also be included, as well as any patent documents from non-U.S. jurisdictions within the same Derwent patent family. Finally, we limited our queries to only patent documents emanating from applications filed after December 1, 2019, the approximate

26. Specifically, the COVID-19 specific query uses Derwent titles, title terms, abstracts, abstract extensions, and the first claim. The COVID-19 related query uses the USPTO publication (either PGPub or patent) title, abstract, claims, and description. Derwent titles and abstracts are created by Clarivate, with the aim of improving patent search, and can differ from the titles and abstracts on patent documents.

27. Note that a similar approach to querying Derwent enhanced abstracts using COVID-19 specific terminology was previously published by others (Lui et al. 2021).

28. Derwent patent families are an extension of EPO Worldwide Bibliographic data (DOCDB) patent families (i.e., the set of documents with the same priorities), to include other patent documents covering the same invention with the same applicant, assignee, or invention (i.e., documents that have a different set of priorities but represent the same invention). More information is available at support.clarivate.com/Patents/s/article/Derwent-Innovation-DWPI-and-INPADOC-Family-Criteria?language=en_US.

start of the COVID-19 pandemic.[29] Our final dataset includes 9,094 COVID-19 diagnostic-specific patent documents and 18,540 COVID-19 diagnostic-related documents. The queries are provided in Table A3.

Table A1. COVID-19 keywords

Keyword	Description
*10covid19*10	Contains "covid19"
*10covid?19*10	Contains "covid-19" or variations
*10covid ADJ 19*10	Contains "covid 19" or variations (with a space)
*5sar*2cov2*5	Contains "sars-cov-2" or variations
*5sar*2 ADJ *3cov2	Contains "sars cov-2" or variations (with a first space)
*5sar*2cov ADJ "2"	Contains "sars cov-2" or variations (with a second space)
*5sar*2 ADJ *3cov ADJ "2"	Contains "sars cov-2" or variations (with multiple spaces)
"COVID"	Exactly "covid"
"Cov2"	Exactly "cov2"
*10nCoV2*10	Contains "ncov2" or variations
(*3sever*3 ADJ2 *3acute*3 ADJ2 *3respirator*3 ADJ2 *3syndrom*3 ADJ2 *10vir*5) ADJ3 ("2" OR "19" OR "2019")	Variations of "severe acute respiratory syndrome virus 2019"
coronavirus NEAR5 "2019"	"Coronavirus 2019" and variations
*5wuhan*5 NEAR10 *5pneumon*5	"Wuhan pneumonia" and variations
*5wuhan*5 NEAR10 *5coronavir*5	"Wuhan coronavirus" and variations
wuhan-hu-1	Exactly "wuhan-hu-1"
novel*3 ADJ (coronav* OR (corona ADJ virus*5))	Variations of "novel coronavirus"
new ADJ (coronav* OR (corona ADJ virus*5))	Variations of "new coronavirus"

29. While we added this condition to reduce the number of patent documents incorrectly retrieved (since those documents filed before the start of the pandemic are unlikely to be related to COVID-19), in practice, very few documents satisfying our set of keywords were actually filed before December 2019.

Table A2. Derwent World Patents Index (DWPI) manual codes (i.e., topics)

Symbol	Definition (see clarivate.com/dwpi-reference-center/mcl/)
A12-V03C2	"Testing, diagnosis, pathology" under "polymer applications"
B12-K* or C12-K*	"Diagnostics, respiratory active type" and subclassifications
B04-E05 or C04-E05	"Primers, probes" under "nucleic acids"
B11-C07* or C11-C07*	"Antibody-antigen reaction, precipitation/colorimetric/fluorescence/radioactive tracer tests, gen." "when diagnosis/testing process forms a novel part of an invention" and subclassifications
B11-C08* or C11-C08*	"Other methods/apparatus for testing/detection" "including new drug screening systems" and subclassifications
S05-D*	"Electrical diagnosis" and subclassifications
S03-E14H*	"Investigation methods for biological material" and subclassifications

Table A3. COVID-19 diagnostic-specific and diagnostic-related queries

Query type	Query text
COVID-19 diagnostic-specific query	ALLD=((*10covid19*10 OR *10covid?19*10 OR (*10covid ADJ 19*10) OR *5sar*-2cov2*5 OR (*5sar*2 ADJ *3cov2) OR (*5sar*2cov ADJ "2") OR (*5sar*2 ADJ *3cov ADJ "2") OR "COVID" OR "Cov2" OR *10nCoV2*10 OR ((*3sever*3 ADJ2 *3acute*3 ADJ2 *3respirator*3 ADJ2 *3syndrom*3 ADJ2 *10vir*5) ADJ3 ("2" OR "19" OR "2019")) OR (coronavirus NEAR5 "2019") OR (*5wuhan*5 NEAR10 *5pneumon*5) OR (*5wuhan*5 NEAR10 *5coronavir*5) OR "wuhan-hu-1" OR (novel*3 ADJ (coronav* OR (corona ADJ virus*5))) OR (new ADJ (coronav* OR (corona ADJ virus*5))))) AND MC=((A12-V03C2 OR B12-K* OR B04-E05 OR B11-C07* OR B11-C08* OR C12-K* OR C04-E05 OR C11-C07* OR C11-C08* OR S05-D* OR S03-E14H*)) AND ADB>=(20191201);
COVID-19 diagnostic-related query	ALL=((((*10covid19*10 OR *10covid?19*10 OR (*10covid ADJ 19*3) OR *5sar*-2cov2*5 OR (*5sar*2 ADJ *3cov2) OR (*5sar*2cov ADJ "2") OR (*5sar*2 ADJ *3cov ADJ "2") OR "COVID" OR "Cov2" OR *10nCoV2*10 OR ((*3sever*3 ADJ2 *3acute*3 ADJ2 *3respirator*3 ADJ2 *3syndrom*3 ADJ2 *10vir*5) ADJ3 ("2" OR "19" OR "2019")) OR (coronavirus NEAR5 "2019") OR (*5wuhan*5 NEAR10 *5pneumon*5) OR (*5wuhan*5 NEAR10 *5coronavir*5) OR "wuhan-hu-1" OR (novel*3 ADJ (coronav* OR (corona ADJ virus*5))) OR (new ADJ (coronav* OR (corona ADJ virus*5))))))) AND AD>=(20191201) AND MC=(((A12-V03C2 OR B12-K* OR B04-E05 OR B11-C07* OR B11-C08* OR C12-K* OR C04-E05 OR C11-C07* OR C11-C08* OR S05-D* OR S03-E14H*)));

II. Validation

Precision and recall are two measures that researchers use to evaluate patent landscapes. Precision measures the share of documents identified in the landscape that actually represent the technology of interest, while recall is the share of documents that are actually in the technology that the landscape identifies.

To assess precision, we randomly sampled 123 documents from the COVID-19 diagnostic-specific query, and 100 from the set of documents that were included in the COVID-19 diagnostic-related query that were not in the specific query. To compute precision for the COVID-19 related query, we averaged precision from these two sets using weights determined by the relative size of both sets in the overall COVID-19 related query. The results are contained in Table A4. The COVID-19 specific query achieves a precision of 0.675, meaning that 67.5% of the documents it identifies as being COVID-19 diagnostics are reasonably classified as COVID-19 diagnostic filings. Extending the query to COVID-19 related documents reduces precision to 0.462. Notice that including these additional documents substantially reduces precision—each additional document has only a 32% chance of being a COVID-19 diagnostic (precision from "COVID-19 related but not specific" in Table A4).

Computing a measure of recall is challenging because we do not have a gold standard set of COVID-19 diagnostics. However, we are able to identify a true set of COVID-19 patent applications that were verified as such during the USPTO's Track 1 COVID-19 program. To assess recall using this set, we compute the share of COVID-19 Track 1 patent documents that are retrieved by our overall COVID-19 keyword sets using both the specific and related approaches (i.e., queried using Derwent versus the full text of patent documents). The documents retrieved from the COVID-19 keywords in the specific query achieve recall of 0.537, while using the related approach achieves recall of 0.860.

The precision and recall results reveal a common tradeoff: identifying more documents as being in the target technology typically increases recall but reduces precision. For much of this report, we chose to analyze the specific query (with higher precision and lower recall) to ensure that the set of documents has a higher likelihood of being specifically related to COVID-19, at the expense of ignoring COVID-19 documents that are potentially only peripherally related.

Table A4. COVID-19 query precision and recall

Query	Precision	Recall
COVID-19 specific	0.675	0.537
COVID-19 related	0.462	0.860
COVID-19 related but not specific	0.320	N/A

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