

Circulating DNA/RNA

Patent Landscape Analysis – June 2021

Which assignees have disrupted the field of circulating DNA/RNA over the past 5 years?

REPORT OUTLINE

- Circulating DNA/RNA
- Patent landscape analysis
- June 2021
- Ref.: KM21003
- PDF >130 slides
- Excel file >2,440 patent families
- €3,990 for a multi-user license



REPORT'S KEY FEATURES:

- **IP trends**, including time-evolution of published patents, and countries of patent filings
- Patents' **legal status**
- Ranking of **main patent assignees**
- **Key players' IP position** and **relative strength** of their patent portfolios
- **Summary of the IP related to the applications:** infectious diseases, cancer, cardiovascular, nervous system or prenatal.
- **Summary of the IP related to the technologies:** extraction or detection and isolation.
- **Analysis of patent litigations and review of key patents.**
- **Excel database** containing all patents analyzed in the report, including applications and technologies segmentations + **hyperlink to updated online database** (legal status, documents etc.)

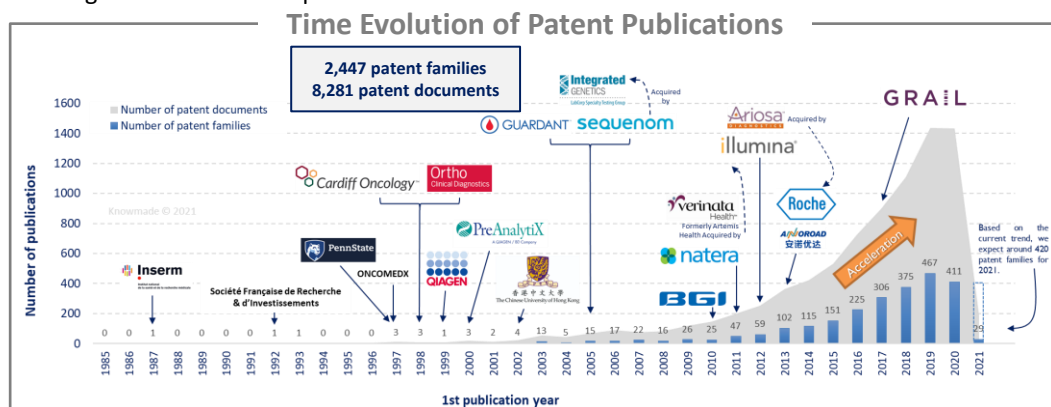
LINKED REPORTS

- [Circulating Tumor Cells: isolation & detection – Patent Landscape 2020](#)
- [Artificial Intelligence in Medical Diagnostics - Patent Landscape 2019](#)
- [Nanopore Sequencing - Patent Landscape 2019](#)
- [Cancer Diagnostics – Startup identification 2020](#)

Circulating nucleic acids tests, an essential step in prognosis and personalized treatment

In clinical practice today, one of the most eagerly awaited technologies is the liquid biopsy, and, more specifically, the analysis of circulating DNA, which is a safer alternative to solid biopsy. It is a useful and essential element for achieving personalized medicine. It is also a minimally invasive approach for diagnosing or prognosing a disease through markers (e.g. mutations) in body fluids such as blood, urine, saliva, cerebrospinal fluid or pleural fluid. Circulating DNA/RNA analysis is not restricted to oncology, though the research and needs in this area are immense and eagerly awaited. This technology is also applicable to prenatal diagnostics, cardiovascular and nervous system diseases or transplantation. In addition, the development of technologies to intercept and analyze these circulating nucleic acids steeply increased in the last 10 years, as did the number of companies supplying them (e.g. Grail, Guardant Health, Roche, Illumina). In the cancer area, great progress has been made in the last 5 years, since 3 medical devices have arrived on the market and have been FDA approved: the cobas® EGFR Mutation Test and FoundationOne® Liquid CDx by Roche; and the Guardant360® CDx by Guardant Health. The FDA has also granted three Breakthrough Device Designations for a Natera test. At the same time, the number of clinical studies observing circulating nucleic acids continues to increase, reflecting the growing interest in this topic as well as the economic stakes for companies. Despite this, multiple issues are delaying the widespread incorporation of ctDNA into routine patient care. Future focus should be on establishing optimal techniques for sample collection, cfDNA isolation and analysis. In addition, further studies are required to better understand the biological characteristics of cfDNA.

In terms of intellectual property (IP), circulating DNA/RNA is of interest to big companies and start-ups alike, and it is crucial to understand the IP position and strategy of these different players. Indeed, significant numbers of litigations and oppositions have been filed recently, showing the strategic role of IP in this area. Such knowledge can help detect business risks and opportunities, anticipate emerging technologies, and enable strategic decisions to strengthen one's market position.



The analysis of the time evolution of patent publications shows that Circulating DNA/RNA started to be investigated in the late 1980s with a first patent published in 1987 by a French Academic player, Insem. Until 2009, there was a latent period, although highly specialized companies in the field started to emerge, such as CLS Therapeutics, Sequenom (acquired by Integrated Genetics) and OncoMEDx. Some academics also started to take an interest in this field of research, such as American universities (Pennsylvania and John Hopkins) and Chinese universities. Since 2010, an acceleration in patenting activity has been observed, with the arrival of big newcomers such as Roche, Natera, Illumina and BGI.

Companies mentioned in this report (non-exhaustive list):

ANNOROAD, AVIIR, BGI, BLUESTAR GENOMICS, CARDIFF ONCOLOGY, CAREDx, CARIS LIFE SCIENCES, CLEVELAND HEARTLAB, EISAI, GRAIL, GUARDANT HEALTH, ILLUMINA, INTEGRATED GENETICS (SEQUENOM), NATERA, ONCOMEDx, PERSONAL GENOME DIAGNOSTICS, PREANALYTIX, QIAGEN, RAVGEN, ROCHE, STRECK.

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AUTHORS**Dr. Fabienne MASSA**

Fabienne works at Knowmade in the field of Biotechnology and Life Sciences. She holds a PhD in Molecular and Cellular Biology from the IPMC (Nice, France). She also holds a Master of Business Management from IAE (Nice, France) and she previously worked in the pharmaceutical industry.

Contact: fabienne.massa@knowmade.fr

**Dr. Brice SAGOT**

CTO and co-founder of Knowmade, Brice leads the Biotechnology and Life Sciences department. He holds a PhD in Molecular Biology from the University of Nice Sophia-Antipolis (France).

Contact: brice.sagot@knowmade.fr

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