



## Global Patent Landscaping: Technologies for Breast Cancer Diagnostics

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**Abstract:** Breast cancer is the most common cancer and the second cause of death in women after cardiovascular diseases. About 12% of women suffer from this disease during their life. If breast cancer is diagnosed at an early stage, its survival rate will be very high. Several methods have been introduced to diagnose breast cancer, each with clinical advantages and disadvantages. Molecular Imaging is one of the major tools used in comprehensive breast cancer care. Despite several aggressive treatment strategies used for breast cancer, the rate of mortality has remained high and thus; there is a need to develop new approaches for cancer management. Recently, research in the field of breast cancer diagnostic technologies has made notable progress, and, with the fast development of it, new treatment strategies are being explored that have the potential to overcome existing problems.

This work offers a complementary perspective to the field of breast cancer diagnostics, focusing on the exploitation of patent and non patent (journal articles) information. In addition, the results have also addressed patent and non patent trend analysis, leading inventor, assignee, applicant and owner, geographical distribution, and technology assessment with respect to CPC international patent classification systems. We expect that systematic understanding of the technology landscape and evolving R&D process in this field may help to provide insights for making future technology planning more rationally.

**Keywords:** Breast cancer, diagnostic, patent landscaping, non-patent literature, CPC classification

### 1. INTRODUCTION

Among all known diseases, cancer is a major health problem and is the second leading cause of death in the United States. The number of new cancer cases increased by about 19.3 million and up to 10.0 million deaths occurred in 2020 (1). Out of all types of cancers, Breast cancer is the most commonly diagnosed and the second most common cause of cancer death in women after lung cancer. As per Cancer Statistics, in 2021 the most commonly diagnosed cancers for women are breast cancer, lung and colorectal cancer (CRCs) account for 50% , out of that breast cancer alone accounting for 30% of female cancers (2). Most women (about eight out of 10) who get breast cancer do not have a family history of the disease. Over 3.3 million breast cancer survivors are alive in the United States today. On average, a woman is diagnosed with breast cancer every 2 minutes and 1 woman will die of breast cancer every 13 minutes (3). In order to cure this disease from its roots, there is a need to diagnose breast cancer in its earliest stage. Extensive research has been conducted to solve the problem of breast cancer, but the solution still remains uncertain. Researchers have studied many breast cancer diagnosed approaches, including mammography (4), ultrasonography, magnetic resonance imaging (5), scintimammography, single-photon emission computed tomography (6), and positron emission tomography (7). Early-stage cancer detection could reduce breast cancer death rates significantly in the long-term. Identifying early-stage cancer cells is critical for an optimal prognosis. Imaging of the breast is utilized almost exclusively for detection, diagnosis, and clinical management of cancer and for the assessment of the integrity of breast implants. Further development in technology will lead to faster diagnosis of breast cancer to meet physiological process requirements.

Recently patent landscaping has emerged as a methodology for analyzing multiple patent documents to uncover technological trends (8), patent trends (9), geographic distribution (10) and number of other uses (11). In other possible words patent landscape analysis is a project consists of a set of technical references and accompanying analytics from which important legal, business, and technology information can be extracted and provides insight into the innovations that underlie

technology and products (12). Such techniques may be used to inform decision making processes, enables large corporations, startups, universities, research institutions, and investors to understand and make informed decisions prior to investing time and money into new technology and product development opportunities (13).

Non-patent literature (NPL) a literature which is publicly available and not a patent or a pending/expired publication in a patent office can be an NPL also plays an important role as patents and can be a potential prior art for invention (14). The NPLs help to identify the key competitors in the domain and market giants with products similar to the inventions; identify different application areas of the invention; identify potential research scholars who can collaborate in proceeding further with invention; identifying any mishaps, such as publishing invention in a journal without any consent etc. The majority of all non-patent references are journal references, which provide ample possibilities for large-scale analyses focusing on the extent to which technological developments are situated within the vicinity of scientific knowledge (15).

According to the data from the Patent Lens, patents and non patent articles for Breast Cancer Diagnosis showed sharp growth in the past couple of decades. However, substantially no patent analysis and non patent analysis have been conducted in this area of rapid growth. In this article our objective is to present a comprehensive overview of the recent patents and non patent literature (journal articles only) of breast cancer diagnostics through patent landscaping (16, 17), that provides a series of key messages to support the application of early-stage cancer detection and help in improving breast screening methods for rapidly diagnosing and managing breast cancer.

## 2. METHODS AND MATERIALS

The identical key word search approach to the patent and non-patent literature performed to identify the “breast cancer diagnosis” in The Lens, formerly called Patent Lens, is an online patent search facility and knowledge resource. Specifically, the following search terms used in the title, abstract and full text:

### Patent Analysis

Patents (2,672) = Title: breast cancer AND ( Title: diagnos\* OR ( Abstract: breast Cancer AND ( Abstract: diagnos\* OR ( Full Text: breast cancer AND Full Text: diagnos\* ))) )

### Scholar Analysis

Scholarly Works (5,005) = Title: breast cancer AND ( Title: diagnos\* OR ( Abstract: breast cancer AND ( Abstract: diagnos\* OR ( Full Text: breast cancer AND Full Text: diagnos\* ))) )

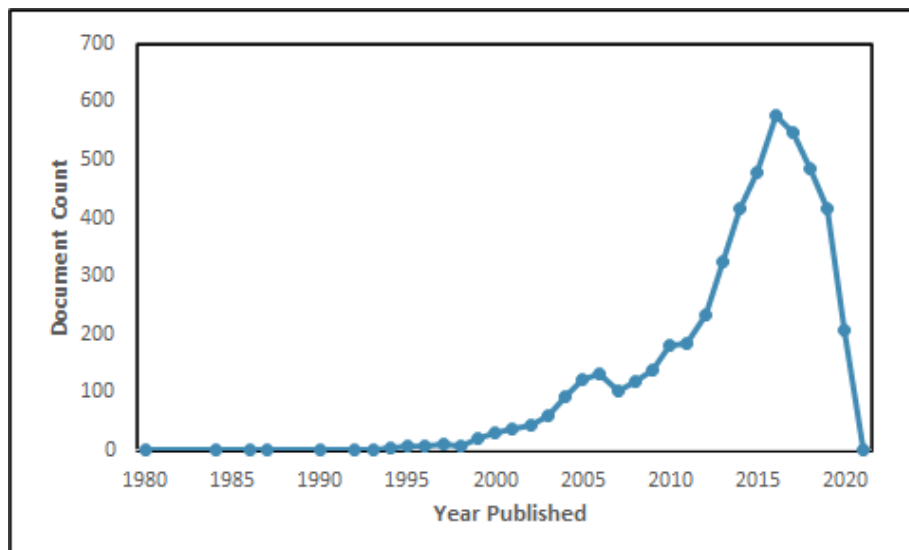
Patented documents result in 2,672 and non-patented (journals articles) documents result in 5,005 hits during approximately the last 40 years. Asterisk (\*) is a wildcard query for multiple character replacements searching for terms that may vary in spelling or to explore a topic before narrowing the focus. Data was downloaded from Lens in csv. files and then microsoft excel was used to create charts based on data obtained from csv.files to generate the figures of this article.

## 3. RESULTS AND DISCUSSION

### 3.1. Trends in Publication:

Fig. 1a shows the number of publications in the field of breast cancer diagnosis from 1980 to June 2021. Till 1998 trend was pretty constant but increased steadily since 1999. A slight decrease was apparent in the year 2007 which again has trended upward since 2008, whereas the year 2011-2016 saw major surges in publication numbers followed by continuous decline, which may be attributed to the emergence and rapid evaluation for the need of breast cancer diagnosis strategies. The 2672 patent family documents from 1980-2021 showing a trend similar to that of publications, with a much higher rate of patenting between 2011-2017, followed by declines in subsequent years. This upward trend reflects that considerable resources have been attracted to this promising field in recent years. The annual growth rate of breast cancer diagnosis related patents, defined as the percentage of increase in patent number over the previous year, is shown in (Fig. 1b). The increasing trend in publications and patents suggests that the intensity of growing interest in the field of breast cancer diagnosis investments by both biotech and pharmaceutical companies.

a



b

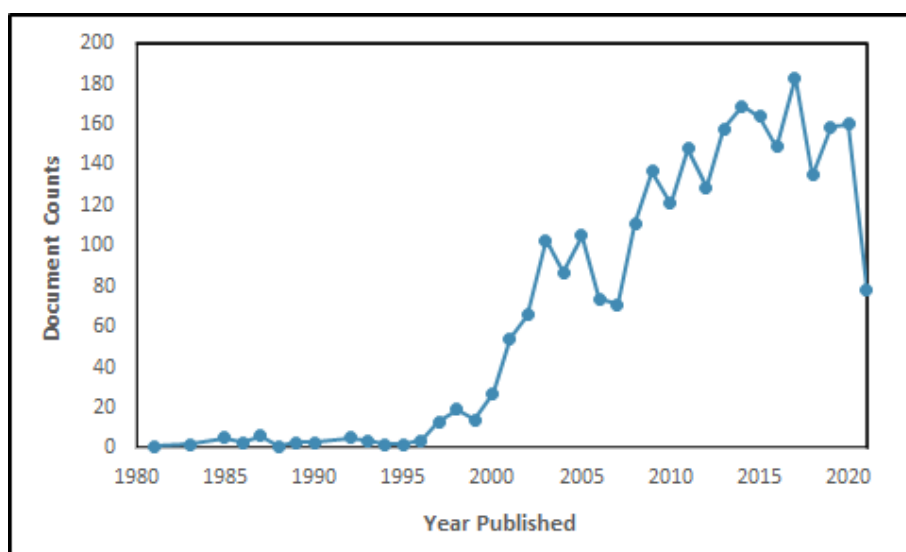


Fig. 1. An overview of the publications and patents related to the “Breast Cancer Diagnosis”.

a) Coverage of journal publications from 1980-2021, b) Coverage of patents and patent applications from 1980-2021.

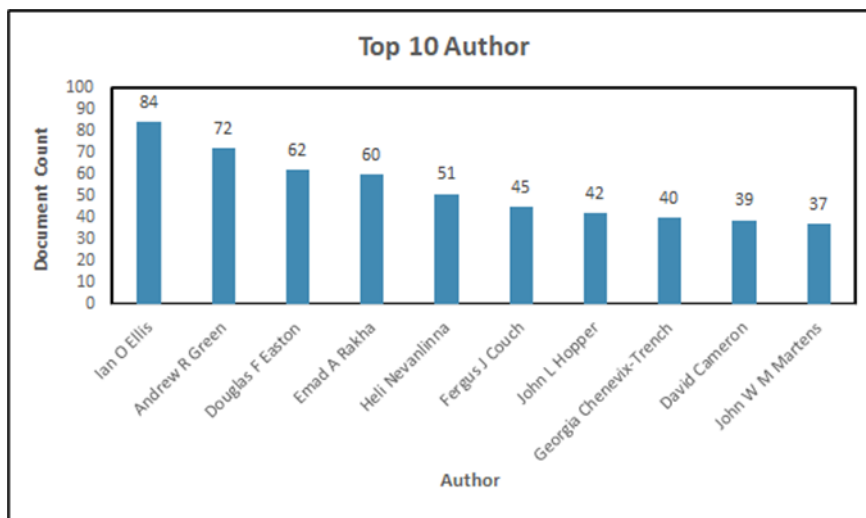
This indicates that breast cancer diagnostics is promising and is being considered to detect breast cancer at earliest manifestation and considered to help in improving breast screening methods for rapidly diagnosing and managing breast cancer. We also analyzed the number of breast cancer diagnosed related publications as non patent and patent publications shows that the growth in applications peaked at year 2016 and year 2017, although the growth of non patent publications has been escalating since year 2008. Usually academic activities lead to industry applications for several years, therefore prognosticate growth in patent number is expected in the years to come.

### 3.2. Top Authors, Inventors, Institutes, Applicants and Owners:

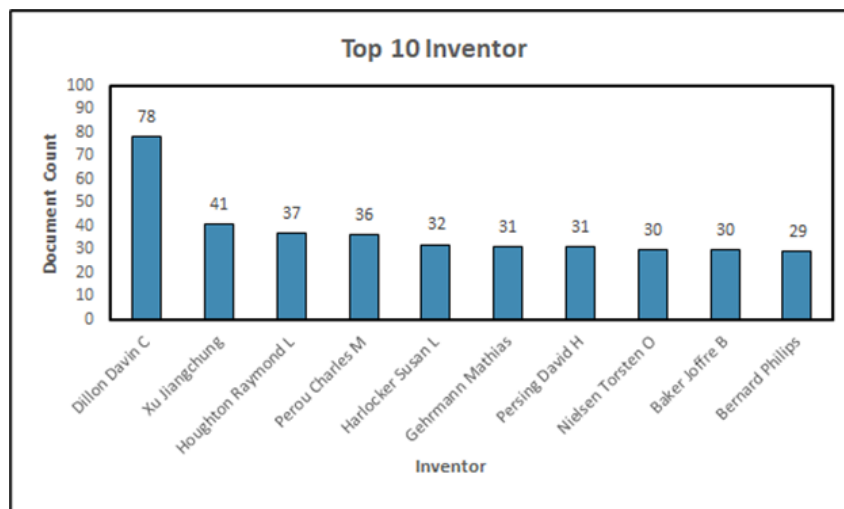
The top 10 authors of journal article publications are shown in Fig. 2a. Five top authors in a field of breast cancer diagnosis are located in the UK, two in Australia, one in US, one in Finland and one in the Netherlands. Among them Ian O Ellis from University of Nottingham has published the highest number of research articles (18). Andrew R Green (19) and Douglas F Easton (20) are second and third respectively. Similarly The inventor analysis was performed on the top ten inventors with patent documents to identify the leading scientist. Fig. 2b. displays the information of top inventors and Dillon Davin C from University of Washington is the leading inventor with 78 patents (21), followed

by Xi Jiangchung having 41 patents from University of Maryland. Houghton Raymond L, Perou Charles M, Harlocker Susan L, Gehrman Mathias and Persing David H are the next active inventors reporting 37, 36, 32, 31 and 31 respectively. Nielsen Torsten O a scientist from University of Vancouver and Baker Joffre B both at international level reporting 30 patents each. The top 10th position is taken by Bernard Philips with 29 patents.

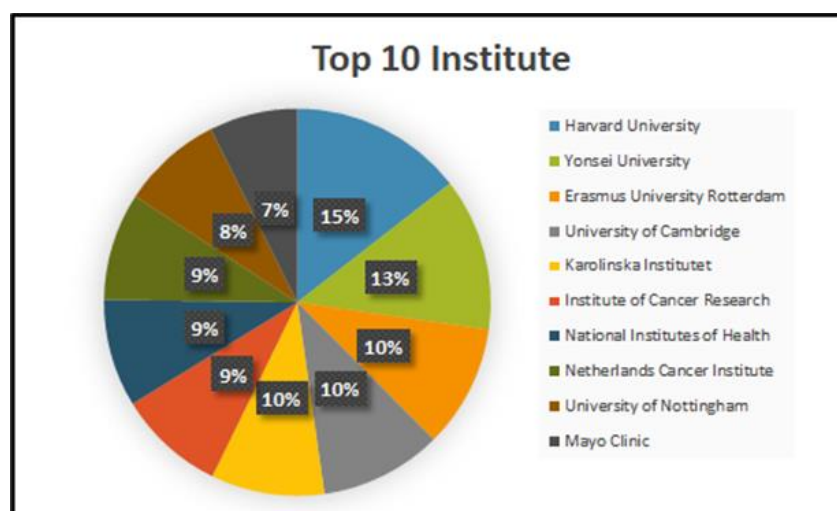
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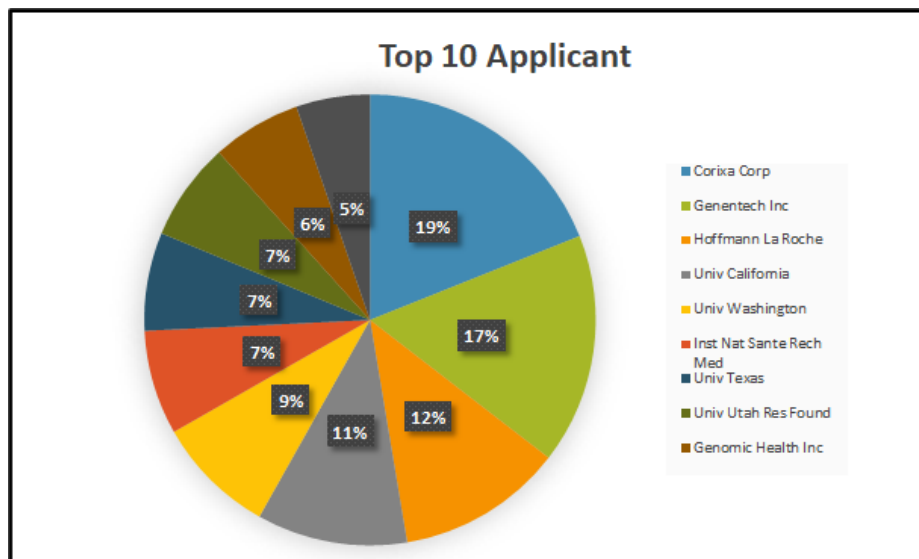
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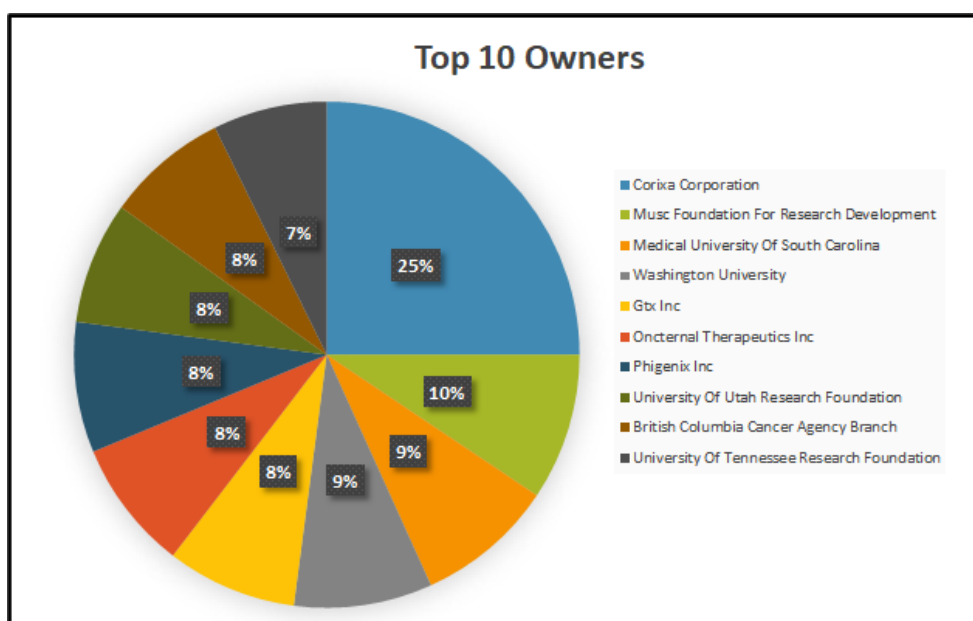
c.



d.



e.



**Fig. 2.** a) Top ten authors with journal publications on breast cancer diagnosis, b) Top ten inventors with patent publications on breast cancer diagnosis, c) Top ten institutions publisher non patent documents on breast cancer diagnosis, d) Top ten applicants with patents on breast cancer diagnosis, and e) Top ten owners with patents on breast cancer diagnosis.

Fig. 2c shows a pie chart representation of top 10 institutes along with their percentile contribution for research articles. As per the given details, the Harvard University is the leading institute reporting 200 publications contributing 15%, followed by Yonsei University, Erasmus University Rotterdam, University of Cambridge and Karolinska Institutet contributing each with 176 (13%), 142 (10%), 141 (10%) and 131 (9%), respectively. These top 10 public funded research institutes and universities are reported as the major research contributors i.e. a total 1380 research articles non patent documents contributing 28%, from our total scholar analysis documents resulting in 5,005 hits during approximately the last 40 years.

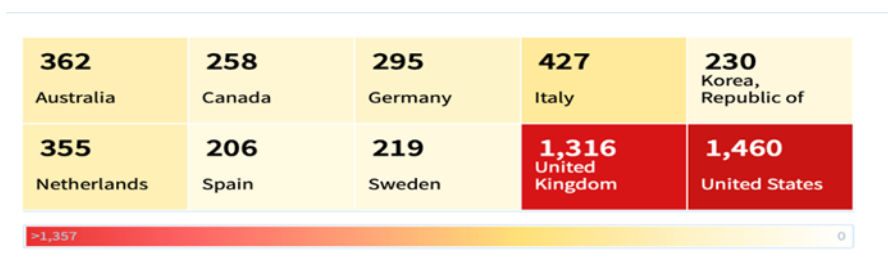
Additionally Fig. 2d shows the top ten patent applicants. Except Inst Nat Sante Rech Med (Inserm) based in France and Oncotherapy Science Inc (Japan), all applicants are from the United States. Four applicants belong from academia, from University of California, University of Washington, University of Texas and University of Utah Research Foundation. Other four applicants are the biotech and pharmaceutical industries.



Fig. 2e focusing on the top ten owners of patents in the United States. Corixa Corporation biotechnology/pharmaceutical company founded in 1994 based in Seattle, Washington, this industry involved in the development of immunotherapeutics to combat autoimmune diseases, infectious diseases, and cancer. This corporation owns the maximum number of patents 48 in the breast cancer diagnosis field. Musc Foundation For Research Development is the second to have 18 patents, Medical University of South Carolina and Washington University are third at place with a total number of 17 patents each. By statistics on the type of patent’s owners commercial companies are dominant, accounting for 40% of the total, followed by Research foundations accounts for 30% , Universities account for 20% and 10% owned by other cancer agencies. Out of 40% commercial agencies, 25% patent owned solely by Corixa Corporation.

**3.3. Geographic Distribution:**

a.



b.



**Fig. 3.** a) Breast Cancer diagnose journal article publications jurisdiction, and b) Breast Cancer diagnose patent documents jurisdiction

To distinguish between market destination and technology origination, we drew the heat map index for jurisdictions that are publishing the research articles and filing patents documents of breast cancer diagnosis field, respectively. Fig. 3a compiles the top 10 countries of publishing research articles. The United States and United Kingdom lead with 1,460 and 1,316 publications, respectively. Italy published 427 followed by Australia and Netherlands 362 and 355 respectively.

Fig. 3b illustrates the geographical areas covered by patent applications represented in the form of heat map index. According to the given data, the maximum number of patent application are reported by the United States, 1531 applications covering 70% followed by WP-WIPO 831 is the second largest and Australia 250 application showing 16% and 11%, respectively, though they still represent half of the total for the United States. Other leading jurisdictions Australia and European Patents have shown relatively slow development.

**3.4. Patent technology analysing using CPC classification codes:**

The Cooperative Patent Classification (CPC) system is jointly developed by the European Patent Office and United States Patent and Trademark Office; it is a more specific and detailed version of the International Patent Classification. Fig. 4 shows the top 10 major CPC classes which are ranked according to their patent count. As per the given results, the invention with respect to the CPC code C12Q1/6886 relevant for measuring or testing processes involving enzymes, nucleic acids or microorganisms have dominated the technology filed with the highest number 1209 of patent documents. Code A 61P35/00 has 1032 documents related to drugs based on chemical compounds, followed by the investigating and analysing materials by specific methods G01N33/57415 is at third leading code with total documents 1020. Whereas, the next dominating technology identified was the pharmacogenomics and oligonucleotides C12Q2600, Mixtures of active ingredients A61K45/06, therapeutic activities A61P43/00 and chemical analysis, detection or diagnosis of biological material

G01N2800/52. Overall the CPC technology classification analysis has made it clear that the technology area with respect to proteins, peptides and immunology topics like antibody and antigen are reported as dominating fields of research areas for breast cancer diagnosis.

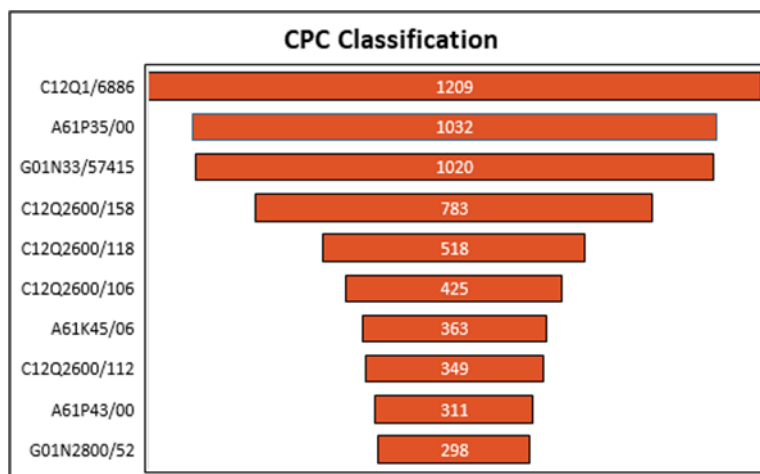


Fig. 4. Breast Cancer diagnoses patent CPC analysis.

#### 4. CONCLUSION

Breast cancer has become a major health challenge in society, but early diagnosis of breast cancer plays an important role in its treatment and control, also helping increase the patient survival rate. Breast cancer diagnosis is a field of cancer treatment with great potential, and the number of patent applications and journal articles are growing rapidly. There are clear signs from the patent landscape analyzed here that the United States is in a leading position and holds the most patents and research articles. Likewise, US companies and their inventors, universities and researches were the most relevant. It clearly indicates that the greatest R&D effort is being put into developing biotech drugs for breast cancer treatment by the United States. This review provided a summary of patents and non patent literature on a single platform. Along with existing evidence on how to appropriately use available techniques, a number of ongoing and future trials will refine the role for diagnosis of breast cancer to optimize the management and quality of life.

The findings of this study should provide useful information for those who will be performing research and studying breast cancer and for prospective models in the study of breast cancer. This work also offers a complementary perspective to the field of breast cancer diagnosis, focusing on the exploitation of patent and non patent information. We expect that systematic understanding of the technology landscape and evolving R&D process in this field may help to provide insights for making future technology planning more rational.

#### AUTHORS' CONTRIBUTIONS

Author Bhushan conceptualized an idea, contributed to the manuscript with the collection of literature and wrote up the article. All authors contributed critical revision, editing, and approval of the final version.

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