Bispecific Antibody & Cancer

Patent Landscape Analysis – January 2025

Bispecific Antibodies Mark a Breakthrough in Cancer Therapy Intellectual Property

REPORT OUTLINE

- Bispecific Antibody & Cancer
- Patent landscape analysis
- January 2025
- Ref.: KM25001
- PDF > 120 slides
- Excel file: 2895 patent families
- €4,990 for a multi-user license

REPORT'S KEY FEATURES:

- **IP trends**, including time evolution of published patents, countries of patent filings and patents' **legal status**
- Ranking of **main patent assignees**
- **Key players' IP position** and **relative strength** of their patent portfolios
- **Segmentation**: Tumor Antigens (ERBB family, BCMA, BRCA, mesothelin, PSMA, CEA, claudin, EPCAM, mucin, NKG2D, VEGF, CEACAM, MAGE, ROR1, c-Met and nectin), Immune Checkpoints (PD1 / PDL1, CTLA-4, LAG-3, TIM-3, OX40, ICOS, B7-H3, TIGIT and BTLA) and T cells (CD3).
- **Analysis of collaborations and EP patent oppositions**.
- **Excel database** containing all patents analyzed in the report, including segmentations + **hyperlink to updated online database** (legal status, documents etc.)

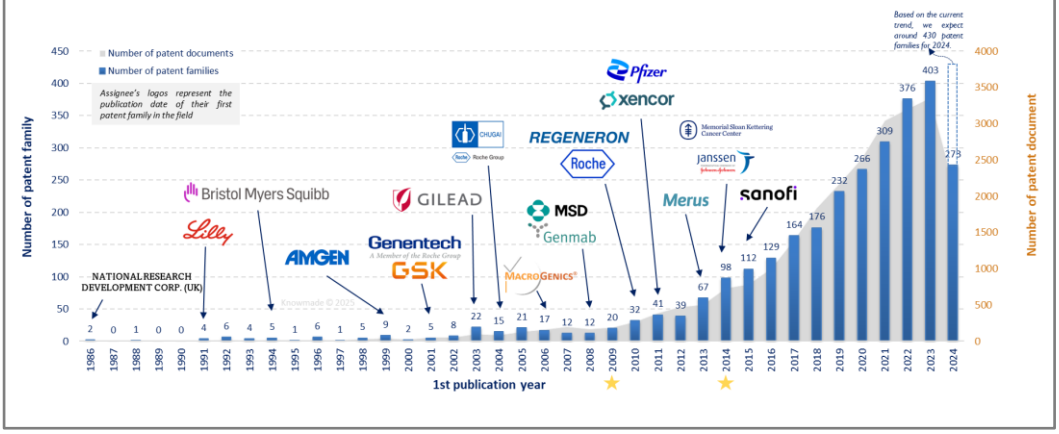
LINKED REPORTS

- Allogeneic CAR Patent Landscape Analysis 2023
- mRNA Cancer Therapies Patent Landscape 2022
- Self-amplifying RNA vaccines Patent landscape 2023
- Circulating DNA/RNA – Patent Landscape 2021

BsAbs offer exciting opportunities for the design and development of new drugs, and are expected to have lasting therapeutic impact

The development of bispecific antibodies (bsAbs) in oncology is experiencing rapid growth, accompanied by significant clinical advancements. According to recent data, more than 85% of bsAbs in clinical trials are cancer treatments, with approximately 600 bsAbs currently in clinical trials. To date, 11 bsAbs have received regulatory approval for use in cancer, ten of them by the US FDA. This expansion reflects the growing interest in these innovative therapeutic agents. Bispecific antibodies are engineered proteins designed to bind simultaneously to two distinct antigens. They can bridge two cell types (in-trans binding) or engage two molecules on the membrane of one cell (in-cis binding). BsAbs that bridge cells represent the largest group, with T cell redirection as the most common denominator. T-cell engagers bind both cytotoxic T cells and tumor cells, promoting a direct immune response against the tumor. Several bsAbs have recently received regulatory approvals. In December 2024, the U.S. FDA granted accelerated approval of a HER2 × HER3 bsAb for adults with advanced, unresectable, or metastatic non–small cell lung cancer (NSCLC) harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy, or advanced, unresectable, or metastatic pancreatic adenocarcinoma harboring an NRG1 gene fusion with disease progression on or after prior systemic therapy. However, challenges remain, such as the complexity of production, toxicities (cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome, infusion-related reactions), and the need to optimize the stability and half-life of the molecules. Innovative approaches, such as advanced antibody engineering technologies and the development of new molecular formats, are being explored to overcome these obstacles. Understanding the intellectual property position and strategy of these various players is crucial in this evolving context. Detecting business risks and opportunities, anticipating emerging technologies, and enabling strategic decisions to strengthen market position can be achieved through this knowledge.

Time Evolution of Patent Publications

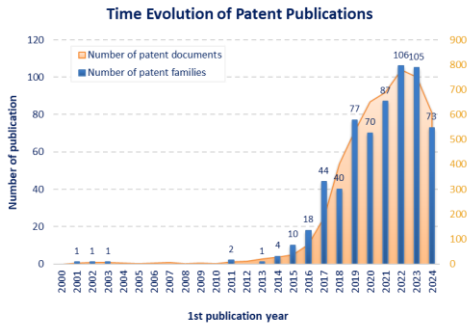


Between 1986 and the early 2000s, the number of patent publications is low but increasing. From 2010, the field is experiencing a significant acceleration, culminating in 2023 with more than 400 patent families. In the 1980s and 1990s and early 2000s, many advances were made in academic research such as the generation of the 1st asymmetric format, the 1st demonstration of T cell redirection, the 1st recombinant fragment-based formats, the 1st solution to light chain (LC) association issue through species-restricted LC pairing, the 1st solution to chain-association issue through use of complementary heavy chain (HC) (knobs into holes) and common LC, the 1st symmetric format, the discovery that natural human IgG4 is bispecific, the dual variable domain-Ig symmetric format pioneered, etc. All these innovations have contributed to the establishment of bsAbs. Then, in 2009, the bsAb catumaxomab (a T lymphocyte antigen CD3 × epithelial cell adhesion molecule (EpCAM)) received the European Union approval for the treatment of malignant ascites. Five years later, the blinatumomab (CD3×B lymphocyte antigen CD19) was FDA approved. It has been approved in the EU in 2015.

Analysis by segment

Bispecific Ab & Cancer have been investigated and the selected patent families labeled according to technologies to which they relate. This IP landscape features the following 3 types of segmentation: **Tumor Antigens** (ERBB family, BCMA, BRCA, mesothelin, PSMA, CEA, claudin, EPCAM, mucin, NKG2D, VEGF, CEACAM, MAGE, ROR1, c-Met and nectin), **Immune Checkpoints** (PD1 / PDL1, CTLA-4, LAG-3, TIM-3, OX40, ICOS, B7-H3, TIGIT and BTLA) and T cells (**CD3**).

Segment Analysis



Assignee (Ranked by strenght score)	Player country	Strength index	Nb of patent families	% of player's stock Portfolio	Nb of patent publications	Number of granted patents: All countries	USA	Europe	Japan	China	Korea	Taiwan	Singapore	India	Number of pending patents: All countries	USA	Europe	Japan	China	Korea	Taiwan	Singapore	India	WO
MACROGENICS	US	1076	14	33%	335	183	17	13	11	8	3	12	4	5	79	7	8	2	3	6	7	3	3	
BMS	US	746	3	9%	53	4	2		1						4		1	1	1					
ROCHE	EP	703	12	18%	420	129	10	17	15	11	5	9	4	2	184	14	28	12	15	14	8	1	4	7
BRIGHAM & WOMENS HOSP	US	422	1	33%	11	7	3		3						1	1								
SANOFI	EP	329	9	25%	88	31	8	4	5	3	3	4	1	1	39	9	7	5	4	1	2		3	1
EPIMAB BIOTHERAPEUTICS	CN	324	6	60%	76	34	4	6	3	2	2	4		2	30	3	7	2	4	2	2		1	1
DANA FARBER CANCER INST	US	315	5	50%	42	12	2	1	1	2	1				23	1	3	2	2	2			1	2
XENCOR	US	306	18	36%	90	24	11	4	2	1	3			1	46	8	8	3	4	3		1	2	7
GENMAB	EP	247	10	17%	160	56	5	7	7	4	2		1	1	95	8	17	5	8	6	2	3	5	4
LEGEND BIOTECH	US	210	8	73%	90	21	6		7	5	1	1			40	1	10	1	3	5	4	3	1	
BIONTECH	EP	203	8	42%	126	49	5	6	6	3	2		1	1	71	7	13	3	6	5	1	2	4	4
MERCK MSD	US	199	6	17%	90	33	6	2	4	2	3	2		1	31	2	7		1	1	1		1	1
AKESO PHARMACEUTICALS	CN	198	15	94%	154	16	1	2	2	4	1		1		130	10	21	9	11	9		1	8	9
MERUS	EP	192	12	34%	154	27	5	6	5	1				1	115	8	15	8	15	8	10	4	8	4
BIOMED VALLEY DISCOVERIES	US	184	1	100%	2																			
REGENERON PHARMA	US	181	10	20%	106	27	3	2	2	1					71	6	9	2	4	5	4	2	4	7
INNOVENT BIOLOGICS	CN	166	15	63%	83	16	2		2	6		6			39	3	7	4	1	4	4	1		1
ASTRAZENECA	EP	163	7	41%	91	19	4	2	2	1	2	2	1	1	52	4	8	3	2	4	5		2	3
INVOX PHARMA	UK	145	4	40%	75	29	1	5	4	3	1	1	1	1	39	4	8	3	1	4	2	1	2	
JANSSEN	US	142	1	1%	67	30	1	2	2	3		1	1	1	18	1	1		1	3			2	
CYTOMX	US	135	1	13%	32	19	1	4	2	1	1			1	6	1	1	1	1				1	

For each segment, the patent publication timeline, patenting strategy and patent portfolios of the main players have been analyzed.

EP oppositions

Currently, there is a significant number of **EP oppositions** which reflects the strategic issues of bispecific antibody & cancer for companies. For each opposed patent, the application date, assignee, opponent, opposition year, and results are detailed.

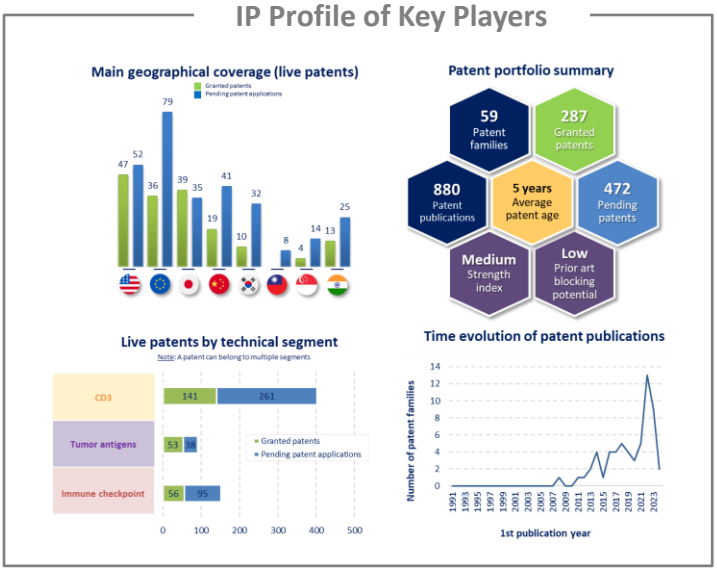
Identifying the companies that have recently emerged in the IP landscape

Among the players owning patent families related to Bispecific Ab & cancer, **52 newcomers** were identified. These companies are either start-up firms (6) or established companies (46) developing their first technology in the field. Most IP newcomers are based in the U.S. and in Asia. It is possible that one of these innovative companies could become one of the next healthcare unicorns that the big corporations will be tempted to acquire.

IP profile of key players

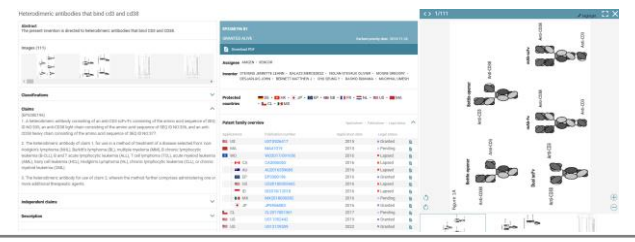
This IP study includes a **selection and description of main players.** The patent portfolio analysis of main players includes a description of the assignee, patent portfolio description, time evolution of patent publication, main geographical coverage and live patents by technical segment. This IP profile overview is followed by the description of the technological content of their key patents and by a table with its clinical trials.

IP Profile of Key Players



Excel Spreadsheet

Online Database



Moreover, the report includes an **Excel spreadsheet** with the **2895 patent families** analyzed in this study. This useful patent database allows for **multi-criteria searches** and includes patent publication numbers, hyperlinks to the original documents, priority dates, titles, abstracts, patent assignees, each patent's current legal status and segmentation. The report also includes a Patent Online Database which legal status are updated for each patent document.

Companies mentioned in this report (non-exhaustive list):
ROCHE, AMGEN, JANSSEN, GENMAB, XENCOR, REGENERON PHARMACEUTICALS, GENENTECH – ROCHE, MACROGENICS, DRAGONFLY THERAPEUTICS, SANOFI, CHUGAI PHARMACEUTICAL, MERCK MSD, MERUS, BMS, SAMSUNG, JIANGSU HENGRUI PHARMACEUTICALS, ABBVIE, HEFEI TG IMMUNOPHARMA, MARENGO THERAPEUTICS, etc.

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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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