Research Report on Global Biosimilars Market

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CERTIFICATE

This is to certify that the report entitled "**Research Report on Global Biosimilars Market**", submitted by Garvita Bansal, Roll No. 602104002, in partial fulfilment of requirements for the award of degree M.Tech in Biotechnology from Department of Biotechnology, Thapar Institute of Engineering and Technology, Patiala is a record of candidate own work carried out by her under my supervision and guidance. The work reported here has not been submitted, either in part or in full, for the award of any other degree in other institute or university.

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DECLARATION

I hereby declare that the thesis report entitled "**Global Biosimilars Market** " submitted by me in partial fulfilment of the requirements for the award of degree of Master of Technology in Biotechnology submitted in the Department of Biotechnology at Thapar Institute of Engineering and Technology, is an authentic record of my work carried out under the supervision of **Mrs. Preeti Swapnil Wani,** and refers other researcher's work which is duly listed in the reference section. I further declare that work embodied in this report has not been and will not be submitted, either in part or in full, in any other institute or university for award of masterand science or any other degree.

Garvita Bansal

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After an extensive period of ten months, I take this opportunity to write this note as a final touch of dissertation to express my gratitude and acknowledge the individuals who have been there for me in the completion of my thesis. These past few months were intense for me not only in the scientific but also on a personal level. The realm of time has taught me a lot and this dissertation has a big impact on me. I would like to commence by thanking the people who helped me throughout this period. Prima face, I would like to thank my mentor and guide Mrs. Preeti Swapnil Wani, (Assistant Manager, Research Nester Analytics LLC) for her valuable guidance and constant support throughout the course of this work. It is my privilege to thank Mr. Gaurav Mitra, Director, Research Nester Analytics LLC forgiving me the opportunities to undertake this project. I would also like tothank my worthy seniors, Mr. Anil Kumar, Ms. Rasika Dandare, Mrs. Ipseeta Dash, Mr. Dhruv Bhatia and Mr. Abhishek Anil Verma for embarking on this journey with me and staying with me till the end. The greatest thanks go tomy family: My parents, Mr. Rakesh Bansal and Mrs. Garima Bansal for all their love and support in each phase of my life. Further, I want to extend my thanks to my friends- Rakshita Bansal, Khwaish Nagar and Jaskiran for their unconditional support. Above all I express my heart-felt gratitude to the almighty for all his blessings.

ABSTRACT

A medication that is extremely similar to a biologic medication in terms of the structure and function is known as a biosimilar or a biosimilar drug. They are produced in a living system, such as mammals, yeast, and the bacterial cells'. One or more biosimilars are offered for various brand-name biologics. A brand-name biologic and a biosimilar have structures that are very close but not identical. Since a biosimilar functions' similarly to its brand-name biologic, there are "no substantial distinctions" between them. This indicates that the biosimilar is regarded as being equally secure and efficient as the biologic. Both originate in biological systems. While not an identical replica of the brand-name medication, a biosimilar is quite similar to it. For interchangeability, a biosimilar requires further FDA approval. Even when biologics are the best treatment for a condition, access to them can occasionally be difficult due to their high price. The Biologics Price Competition, and, Innovation Act was passed by Congress to lower the cost of biologic medications, and, increase its accessibility to more people (BPCIA). The FDA was able to shorten the approval procedure for biosimilars because to this statute.

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INTRODUCTION

1.1 Overview of Research Nester Analytics LLC

Research Nester, is a one-stop shop for services, specializing in strategic market research, and consulting with an objective & unmatched approach to assist global market players, conglomerates, & executives, by offering them enlightening industry insights and plans while avoiding unforeseen scenarios, the company helps businesses make wise decisions for their future investment and progress. Through its unparalleled expertise, the organization provides market intelligence services to sectors as listed below:

- Healthcare and pharmaceuticals; information technology and telecommunications; and BFSI and other services.
- Packaging; Agriculture and Allied Activities; Chemicals and Advanced Materials
- Minerals, metals, and mining; manufacturing and construction; electronics and smart devices; industrial automation and equipment; and defense, marine, and aerospace

1.2 What is Market Research?

Through interviews with prospective customers, market research examines the potential of a novel good or service. This method can be used by businesses or organizations to determine their target market, collect and record feedback, and arrive at informed conclusions. Businesses and organizations can conduct market research themselves, or they can hire specialized firms to do it on their behalf. Conducting market research, can be done in a variety of methods, including implementing surveys, talking to a sample of people, conducting interviews, and other similar activities. Understanding or evaluating the market for a specific commodity or service, & predicting the behavior of the target market are the basic objectives of analysis of the market. Market research data can be used to create unique marketing and advertising strategies, as well as to pinpoint the aspects that customers value the most and any unmet service demands.

The best methods to improve satisfaction of the customer, lower the customer turnover, & grow the organization is through research. The following categories are available depending on the procedures and equipment needed:

Using both qualitative and quantitative research, conduct primary market research.

- **Primary Market Research** – It is the process through which businesses or organizations interview potential customers or engage a third party to carry out relevant studies to obtain data. Quantitative or qualitative (non-numerical) (numerical or statistical data) information may have

been acquired. Primary market research can be used to acquire both exploratory and particular information. In exploratory research to study an issue, open-ended questions are posed in-depthly to a small number of people, sometimes referred to as a sample. The study's sample size is restricted to 6–10 people. On the other hand, specific research is more narrowly targeted and utilized to address the problems brought up by exploratory research.

- **Secondary Market Research -** This kind of research makes use of information gathered by non-market institutions including government agencies, the media, chambers of commerce, etc. This information is published in newspapers, periodicals, books, corporate websites, free government and nongovernment organizations, and other media.

Three sorts of main sorts objectives are frequently included in the market research projects:

Administrative: Facilitate a company's or business's growth through efficient planning, coordinating, and administration of both human and material resources in order to timely satisfy all unique market demands.

Social: Providing necessary goods or a service that satisfies clients' particular demands. When used by a customer, the product or service should meet their needs and preferences.

Economical: Determine the economic likelihood that a business will succeed or fail when it enters a new market or otherwise introduces new goods or services. This will give all future decisions confidence.

CHAPTER 2

PROCEDURE

In this chapter, the details of procedure to prepare the research report on global biosimilars market is presented. A brief explanation of the techniques used in this work is given.

2.1 Define the Problem

The global biosimilars market was defined as to what is the market all about, and research was done for the same through open end search.

2.2 Data Collection

The data for global biosimilars market was collected through various sources such as primary and secondary sources. A survey questionnaire was prepared, some of the experts were approached in the field to get some insights on the market.

Survey Questions	Option		
On average, what is the cost per biosimilar drug?	$100-$200	$200-300$	$300-$500
Survey Response	XX%	XX%	XX%
On average, how long does it take to complete one biosimilar workflow? (Approximate)	1-2 years	2-6 years	7-8 years
Survey Response			
What precautions your organization takes clinically (Approximate)			
Survey Response			

Fig 1.1: Representation of survey questionnaire

2.3 Market Segmentation

The data was also collected from open end search and then the market segmentation was prepared. The market segmentation for this market is as follows,

By Product

- Monoclonal Antibodies
  - Infliximab
  - Retuximab
  - Adalimumab
  - Trastuzumab
- Glucagon
- Insulin
- Erythropoietin
- Interferon
- Calcitonin
- Others

By Geography

- North America
  - U.S.
  - Canada
- Europe
  - U.K.
  - Germany
  - France
  - Others
- Asia Pacific
  - China
  - India
  - Japan
  - South Korea
  - Others
- Rest of the World

By Application

- Oncology
  - Lung Cancer
  - Brain Cancer
  - Breast Cancer
  - Cervical Cancer
  - Colorectal Cancer
  - Leukemia or Blood Cancer
  - Others
- Growth Hormonal Deficiency
- Blood Disorders
- Chronic & Autoimmune Disorders

- Infectious Disease
- Others
- Autoimmune disease
    - Arthritis
        - Rheumatoid arthritis
        - Psoriatic arthritis
        - Others
    - Inflammatory Bowel Disease (ibd)
    - Psoriasis
    - Others
- Hematology
    - Neutropenia
    - Anemia
    - Others
- Others

2.4 Company Profiling

After the segmentation, the major players/competitors in the market were searched and they are as follows:

- Biogen Idec, Inc.
- Novartis
- Teva Pharmaceutical Industries Ltd.
- LG Life Sciences
- Biocon
- Hospira
- Synthon Pharmaceuticals, Inc.
- Merck Serono
- Biogen Idec, Inc.
- Genentech
- Celltrion
- Other Major Players

These players were then profiled. The companies benchmarking and profiling was done considering certain parameters like the information was taken from the company's official website itself for its validation. The information provided while profiling was as follows:

- About the company
- The key acquisitions
- Product offerings and its description
- Financials of the company

Then, the regulatory and standards framework was analyzed. For ex. - Among the regulatory agencies in this sector for the approval of biosimilar medicines are the US Food and Drug Administration and the European Medicines Agency.

When a biosimilar is given its initial FDA approval, it cannot be used in place of the biologic that carries its brand name right away. Although after receiving initial FDA permission, biosimilars can be used to treat diseases, they need an extra, special FDA approval before they can be automatically substituted for a name-brand biologic. If the biosimilar is not accepted as interchangeable with the brand-name biologic, a prescription must be written specifically for it to be used in place of the original biologic. A biosimilar must follow strict FDA guidelines in order to be recognized as interchangeable. Any biosimilar that has been approved for usage has proven in clinical trial data to be just as safe and effective in treating a particular condition as the original biologic. The biosimilar's manufacturer has the option of just giving the FDA the necessary information for this initial clearance. However, if a company wants the FDA to accept its biosimilar as interchangeable (and hence allow it to be used automatically in place of its brand-name prescription), it must provide additional data from clinical trials. Vegzelma, Stimufend, Cimerli, and other examples come to mind.

2.5 Industry Supply Chain Analysis

Fig 1.2: Representation of industry value chain

The organizations tasked with providing those biosimilars to the end-users, i.e., the customers, are known as suppliers/distributors. Biosimilars are prepared and produced by corporations known as manufacturers.

For ex., in the case of biosimilars, the supply chain will be as follows:

2.6 SWOT Analysis

The market growth drivers, restraints, trends and opportunities were analyzed.

Growth Drivers:

The usage of biosimilars in a variety of the applications

Based on application, the biosimilars market is divided into sections for hematology, oncology, autoimmune diseases, growth hormone deficiency, diabetes, and other conditions. With a market value of USD 13,600 million in 2021, the hematology sector was responsible for about 45% of total revenue. These drugs are used in hematological illnesses, including leukemia, and for hematopoietic malignancies such as cancer. Rituximab is a well-known treatment for both non-Hodgkin lymphoma (NHL) (CLL) and chronic lymphocytic leukemia. According to the Leukemia & Lymphoma Society, lymphoma cases increased by more than 900,000 in only 2021. The global increase in the prevalence of is strongly associated with the increased demand for biologic medical products. According to the Leukemia & Lymphoma Society, lymphoma cases increased by more than 900,000 in only 2021. The rising prevalence of leukemia is directly associated to the increased need for biologic medical products globally, which is expected to drive market expansion throughout the study period.

Cost-effectiveness of the biosimilars prevalent among the global population in the treatment of various chronic diseases

It is anticipated that the adoption of biosimilars would pick up speed quickly in light of the rising prevalence of chronic diseases in the population and the recent regulatory body approval of a variety of biosimilars in a number of countries. Because more people are becoming aware of the availability of biosimilar medicines and their effectiveness in treating a range of conditions, the market for biosimilars is expanding globally. Biosimilars can successfully cure a variety of chronic illnesses, including renal failure, diabetes, cancer, and cardiovascular disease, which is anticipated to fuel market expansion in the years to come. According to the International Agency for Research on Cancer, there will be 10.3 million cancer-related deaths and 19.3 million new cases of cancer worldwide in 2020.

Regulatory reforms

Recently, it is anticipated that the adoption of biosimilars would expand due to regulatory improvements in countries like the US, China, and Japan. Over 60 biosimilar products have already received approval from Europe, which represents over 50% of the market's worth. In the US, seven biosimilars were authorized by the FDA in 2018. Therefore, it is anticipated that regulatory reforms in the key markets will have a beneficial effect on market growth and offer the market's players lucrative growth prospects in the near future.

Restraints: Complexities in the manufacturing

The development of biosimilars is a very complex and expensive process that necessitates significant investments, technical capabilities, clinical trial experience, scientific standards, and quality systems. As a result, the production of biosimilars, or the ability to control variability during the manufacturing process, represents a significant challenge. (Danese, 2017)

Trends: Demand for recombinant glycosylated proteins due to rising adoption of cancer treatment

By assisting the bone marrow in the production of fresh granulocytes, filgrastim is primarily used to treat neutropenia brought on by cancer treatments. In the treatment of cancer patients, filgrastim plays a significant role in supportive therapy. For instance, the American Cancer Society estimates that in 2022 there will be 60,000 new instances of leukemia and about 2,000 new cases of breast cancer in the United States. As a result, there is a growing need for recombinant glycosylated proteins. (Scott Morton, 2018)

Opportunities: Patent Expiry of Blockbuster Drugs

Blockbuster medicine patents will expire, giving manufacturers the green light to create new products. For instance, it was recently demonstrated in July 2021 that roughly 15 best-selling medications, including Humira and Keytruda, will lose their patents in the ensuing ten years. Because of the patent's expiration, the market for later entry biologics is thus poised for significant growth. (Agbogbo, 2019)

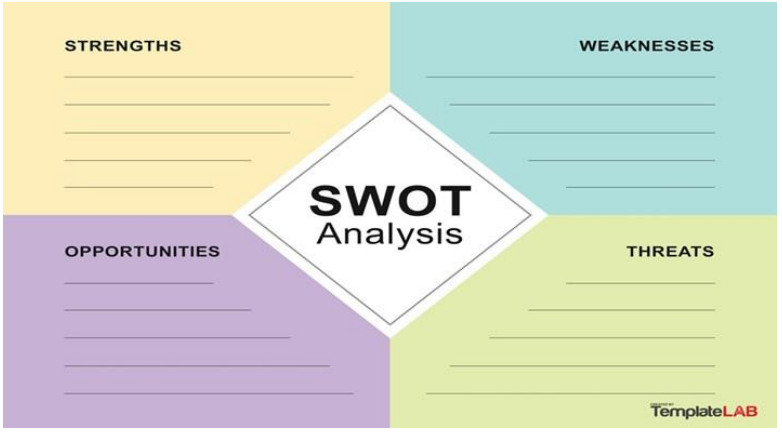

Fig 1.3: Representation of SWOT analysis

2.7 Country-Wise Demand Analysis

For the forecast period of 2022-2035, the market demand is examined by country, including North America, Europe, Asia Pacific, Latin America, and the Middle East & Africa. According to the segmentation in USD Million and Million Units, the market's revenue and volume are examined. The following formula is used to determine market value:

Market size = product mix * penetration rate.

Market value = market volume - average value.

In terms of revenue share, North America now dominates the global market for biosimilars, and it is expected that this trend will hold during the estimated period as well. The prevalence of numerous chronic illnesses among the local population, which is on the rise, is the source of this domination.

It was calculated that the market size for global biosimilars market in the year 2021 was ~USD 30,023.7 Million and 2030 market value projection is ~USD 100,643.9 Million.

2.8 Industry Growth Outlook

The market for biosimilars is predicted to grow as more popular and successful biologic medicines lose their patent protection in the future years. This is because a market for biosimilars, less expensive biologic alternatives, opens up when the patents on biologics expire. To define the industry growth outlook, certain parameters were taken into consideration such as:

1. Product growth forecast (CAGR) 2023-2035
2. Product development opportunity analysis
3. Product investment analysis
4. Product regional demand analysis

2.9 Clinical Trials Analysis

Many clinical trials are taking place in the biosimilars market. Some of them are listed below:

- The Cancer Institute and Hospital of Tianjin 16 Medical University is evaluating the Hepatic Arterial Infusion Chemotherapy (HAIC) Combined with Sintilimab and Bevacizumab Biosimilar in the First-Line Treatment of Patients with Advanced Unresectable Hepatocellular Carcinoma. The clinical experiment's second phase has over.
- Gedeon Richter Plc. is evaluating RGB -14- P's efficacy, pharmacodynamic (PD), safety, tolerability, and immunogenicity in postmenopausal osteoporosis patients in comparison to

Prolia, a drug having a US license. The clinical trial's third phase is now complete. (Udpa, 2016)

- The Korean Cancer Study Group is researching the effects of Trastuzumab Biosimilar (Herzuma) combined with Gedatolisib in patients with metastatic breast cancer who tested positive for HER-2 and progressed after receiving two or more HER-2 focused chemotherapy treatments. The clinical trial is in its Phase 2.

2.10 Recent developments in the market

- On February 2, 2022, Health Canada authorized ONTRUZANT (also known as SB3), a biosimilar to Herceptini (Trastuzumab), for the treatment of adults with early breast cancer (EBC), metastatic breast cancer (MBC), and metastatic gastric cancer. (MGC).
- Senju Pharmaceutical Co., Ltd. was given the go-ahead to sell ranibizumab BS intravitreal injectable kit 10 mg/mL 'Senju', an ocular VEGF inhibitor, in Japan in September 2021 (Blackstone, 2013)
- A strategic partnership between Teva Pharmaceutical Industries Ltd. and Bioeq AG ("Bioeq") was established in June 2021 for the purpose of commercializing FYB201, a biosimilar candidate to the drug Lucentis (ranibizumab), exclusively in Europe, Canada, Israel, and New Zealand.
- Cipla Gulf, a division of Cipla Limited, increased its collaboration with Alvotech in March 2021 to commercialize and distribute four biosimilar medications in Australia and New Zealand. Aflibercept (Eylea), Ustekinumab (Stelara), Denosumab (Prolia, Xgeva), and Golimumab (Simponi), biologic medication brands created and produced by Alvotech, will have patented biosimilars that Cipla Gulf will be in charge of commercializing.

As a result of these industry developments, the market for biosimilars will experience substantial expansion throughout the forecast period.

2.11 Active Patent Analysis

Patent No.	Title	Current Assignee	Estimated Expiration Date	Description
AU2017246460B2	Reducing tumor burden by administering CCR1 antagonists in combination	Chemocentryx Inc	6th April, 2037	In a person with a solid tumor malignancy, like triple negative breast cancer, the

	with PD-1 inhibitors or PD-L1 inhibitors			present invention offers techniques for lowering tumor burden, tumor development, tumor progression, and/or metastasis. The procedures comprise giving a subject who needs it an effective dose of a PD-Ll inhibitor or a PD-1 inhibitor along with a CCR1-blocking small molecule chemokine receptor antagonist.
US10716854B2	Stable aqueous formulations of adalimumab	Coherus Biosciences Inc	6th September, 2033	Adalimumab aqueous pharmaceutical compositions appropriate for long-term preservation are offered by the invention, along with production processes, administration

				techniques, and kits containing the compositions.
US11407723B2	Selective histone deacetylase inhibitors for the treatment of human disease	Shuttle Pharmaceuticals Inc	16th January, 2039	In order to treat cancer, inflammatory illnesses, neurological ailments, and immunological diseases, this article discusses selective HDAC inhibitors and pharmaceutical formulations that incorporate them.

2.12 New/Upcoming Product Launches

Molecule	Innovator Product (company)	Upcoming Biosimilars	Company	Launch Date/Status
Omalizumab	Xolair (Genentech)	TEV-45779 CT-P39	Teva Celltrion	3rd-phase trials 3rd-phase trials
Denosumab	Prolia (Amgen)/ Xgeva (Amgen)	GP2411 FKS518 AVT03 BMAB-1000 Others	Sandoz Fresenius Kabi Alvotech Biocon	3rd-phase trials 3rd-phase trials 3rd-phase trials 3rd-phase trials 3rd-phase trials
Insulin aspart	Novolog (Novo Nordisk)	MYL-1601D AMP-004	Biocon Amphastar	2023 pending FDA approval 3rd-phase trials

		SAR341402	Sanofi	3rd-phase trials
Adalimumab	Humira (AbbVie)	Amjevita Cyltezo Abrilada Yusimry Others	Amgen Boeheringer Ingelheim Pfizer Coherus	 2023 2023 2023
Ustekinumab	Stelara (Janssen)	ABP 654 CT-P43 FYB202 Others	Amgen Celltrion Formycon	 3rd-phase trials 3rd-phase trials

2.13 Biosimilars Industry Segmentation

According to the scope of the report, a biosimilar is a biologic that is "similar" to another biologic drug (referred to as a reference product) that has already gained FDA approval.
In terms of safety, purity, and potency, biosimilars are quite comparable to the reference product; nonetheless, there may be slight variations in components that are clinically inactive. The FDA may demand a clinical trial (or studies) sufficient to show safety, purity, or potency in one or more uses for which the reference product is licensed and the biosimilar requests licensure before approving a biosimilar. (Chow, 2013)

The biosimilars market is segmented into different groups based on the product (monoclonal antibodies, recombinant hormones, immunomodulators, anti-inflammatory agents, and other product classes), the application (blood disorders, growth hormone deficiency, chronic and autoimmune disorders, oncology, and other applications), the geography (North America, Europe, Asia-Pacific, Middle East and Africa, and South America), and the end user (users).

In 2022, the market for monoclonal antibodies held the largest revenue share by product. Monoclonal antibodies are used to treat a wide range of disorders, such as cancer, rheumatoid arthritis, cardiovascular conditions, and multiple sclerosis. This market segment has developed into the most significant due to the extensive use of monoclonal antibodies in the treatment of cancer, which selectively target particular infected cells.
Erythropoietin is predicted to grow at the quickest rate during the prediction period. Erythropoietin

assists in the production of red blood cells in the bone marrow. Additionally, it effectively treats anemia. It is anticipated that there will be more kidney-related illnesses, which will drive the growth of this market.(Jacobs, 2016)

The key factor driving the studied segment's growth throughout the forecast period will be the rising prevalence of cancers globally, and the oncology segment is expected to account for the biggest application share in the biosimilars market. In 2020, there are expected to be 474,519 new cases of leukemia worldwide, according to the International Agency for Research on Cancer 2020. According to the same source, the illness had an extremely high death rate and killed a total of 311,594 lives globally. In addition, the International Agency for Research on Cancer (IARC) projects that by 2040, there will be 27.5 million additional cases of cancer worldwide in addition to 16.3 million cancer-related deaths. The demand for sophisticated cancer therapies is expected to rise as the number of cancer patients rises. Rising regulatory body approvals and increased R&D activities by top oncology-focused companies are also projected to promote the expansion of the examined market. For instance, the US Food and Drug Administration (USFDA) in December 2020 approved Amgen's RIABNI (rituximab-arrx), a biosimilar to Rituxan (rituximab), for the treatment of adult patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, granulomatosis with polyangiitis, and microscopic polyangiitis. Additionally, in May 2022, Biocon Biologics Ltd. and Viatris Inc. received approval from Health Canada for Abevmy (bevacizumab), a biosimilar to Roche's Avastin (bevacizumab), across four cancer indications. Because of the aforementioned reasons, it is anticipated that the oncology section would significantly grow throughout the projection period. (Gulacsi, 2015)

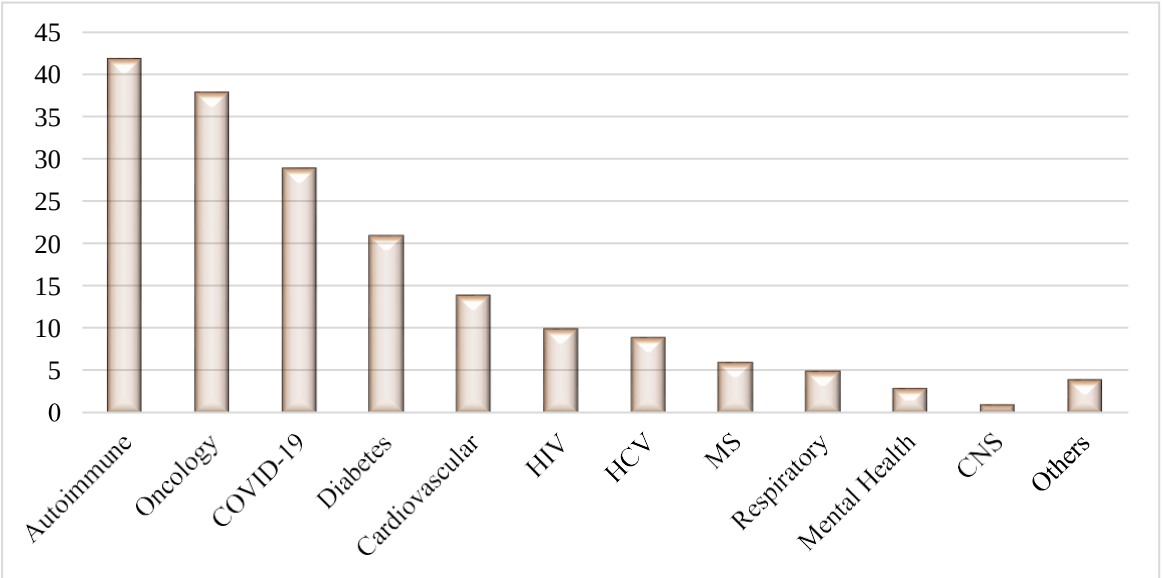

Fig 1.4: US Net Spending Growth for New Brands and Protected Brands Volume, in USD Billion, from 2017 to 2021

North America is expected to see a significant CAGR in the biosimilars market over the course of the projected period. The key factors driving the rise of the region's market under investigation are the high frequency of chronic diseases, such cancer, and the increased spending on research and development activities by the top businesses. According to GLOBOCAN 2020's projections, there will be 2,281,658 new cases of cancer identified in the United States in 2020, with 612,390 cancer-related fatalities. With 253,465 cases, breast cancer had the highest incidence of all malignancies. Lung cancer (227,875), prostate cancer (209,512), and colon cancer (101,809) were the next most common cancers.

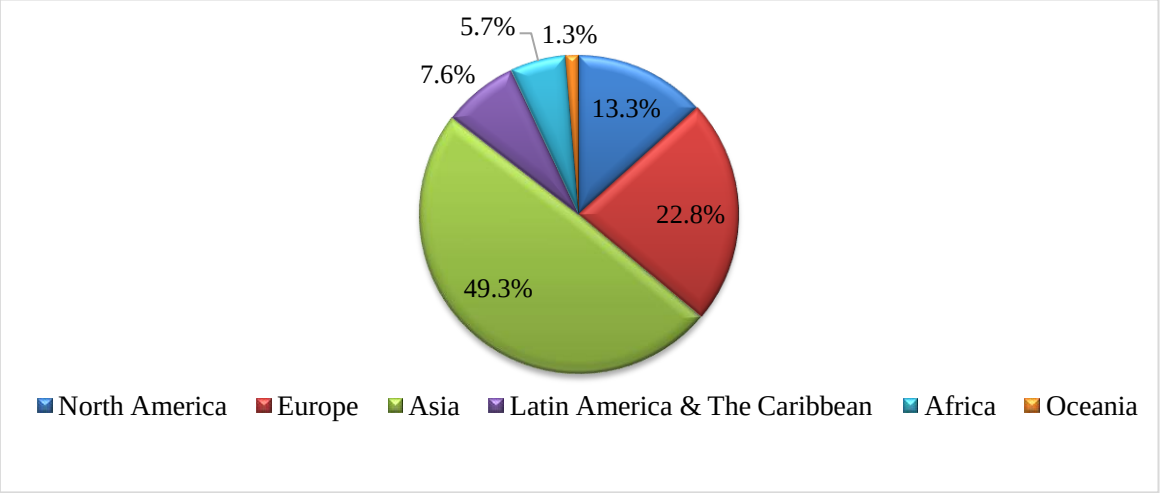

Fig 1.5: % of Cancer Cases Worldwide in 2020, By Region

Numerous prominent market players are headquartered in North America, including Pfizer Inc., Mylan NV, Amgen Inc., and Coherus Biosciences Inc. The market in the region is growing as a result of new product debuts and an expanding product pipeline. For instance, Nyvepria, a Pfizer Inc. pegfilgrastim biosimilar that is suggested for lowering infection incidence, was given U.S. approval in June 2020. The US Food and medicine Administration ("FDA") has also accepted the 351(k) Biologics License Application ("BLA") for CHS-1420, a potential biosimilar replacement for the anti-inflammatory medicine Humira (adalimumab), for review, according to information provided by Coherus BioSciences, Inc. in February 2021.

The market is anticipated to expand significantly over the anticipated period in North America because to the increased prevalence of chronic diseases like cancer and expanding R&D initiatives. (Garcia,2016)

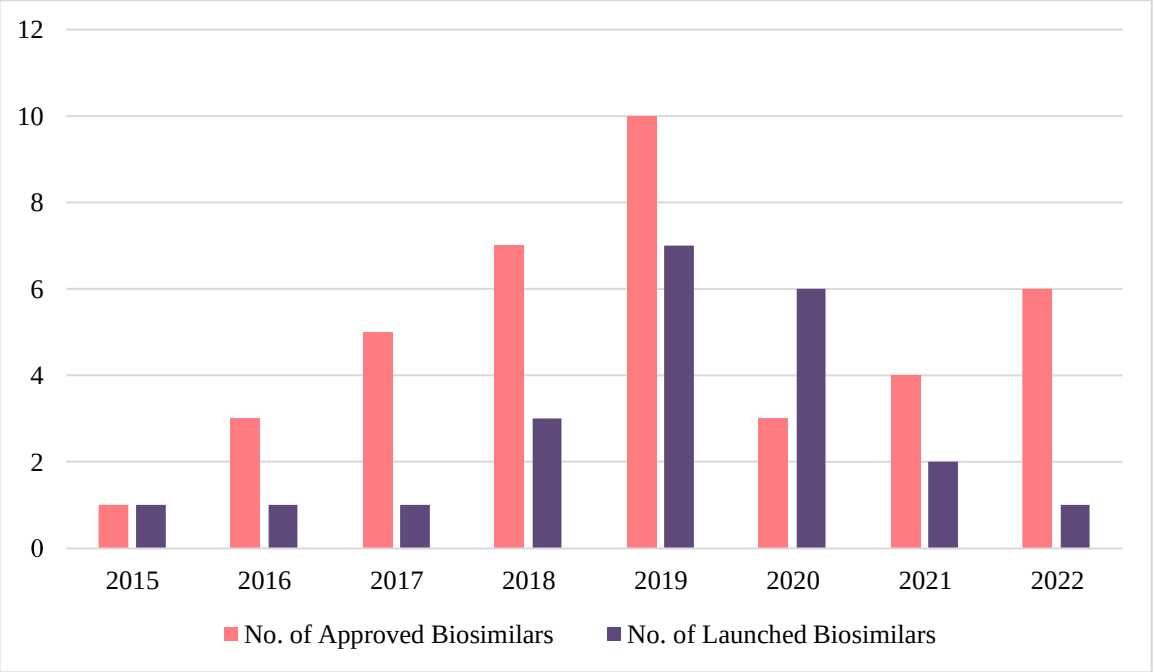

Fig 1.6: Number of Biosimilars Launched and Approved in the US, Yearly

CHAPTER 3

RESULTS & DISCUSSIONS

In this chapter, the results of the analysis made on the biosimilars market have been presented. The study of the ongoing and upcoming trends and new developments in the market has also been given.

3.1 Biosimilars uptake varies by market and molecule

Recent research have shown that switching from original pharmaceuticals to biosimilars typically has little change in clinical efficacy and safety. Many countries presently support physician-led switching to biosimilars, and it is anticipated that switching among pharmacies, pharmacy benefit managers, and other reasons will increase.

The adoption of biosimilars has surpassed 46% by volume across all compounds in developing European markets. This total conceals significant variations in uptake between specific markets and compounds due to varying policies, tender usage, pricing and reimbursement, and prescriber education.

In the US, the Food and Drug Administration (FDA) approved seven biosimilars in 2018, which is almost as many as in the three years before. In 2019, an additional eleven biosimilars received approval. The FDA also published interchangeability criteria for biosimilars, which provide extra clarity for biosimilars businesses when creating new products. The cancer biosimilars have shown how recently announced biosimilars can be adopted significantly more swiftly as a result of this enhanced clarity on legal and regulatory issues, managing to reach nearly 50% of the market within 12 months—even quicker than European averages.

Additionally, better financing has contributed. The most cost-effective drug for outpatients can now be found through step therapy, for example, and biosimilar drugs are now included within the coverage-gap discount scheme for prescriptions alongside brand-name medications. Up until now, doctors' offices have largely controlled the buy-and-bill channel used in the US biosimilars market. According to studies, six to eight biosimilars to adalimumab are predicted to be introduced in the United States in 2023. These products are predicted to operate through the retail pharmacy channel and capture as much as $18 billion in market share by 2025. (Barbier, 2020)

Since local "bio copies" were legalized in the 1990s without direct comparisons to the original drugs, the Chinese biosimilars industry has been in existence. The first four biosimilars were approved in 2019 under a stringent new mechanism put in place in 2015. Following the addition of rituximab and trastuzumab in 2017, the following medications were added to the National Reimbursement Drug List in 2019: adalimumab, infliximab, tocilizumab, golimumab, pertuzumab, aflibercept, and omalizumab. The market will be able to expand even further thanks to these additions, which have enhanced the use of biologics. According to estimates, China is actively developing 400 distinct biosimilar products.

Although the launch of biosimilars for large patient populations in Japan has been gradual, this could speed the market's growth. The penetration of self-injecting biosimilars has also been encouraged by recent legislative changes. For instance, the new rules issued by the Japanese Ministry of Health, Labor, and Welfare in April 2020 provide incentives for medical centers to suggest these drugs. It is anticipated that the level of acceptability for biosimilars will vary based on the molecule and heavily depend on prescription and use incentives.

No matter what markets a biosimilars company competes in, we believe that the key to building and maintaining a viable business will be to reevaluate its marketing approach, portfolio management, and speed to market.

3.2 Commercial model: Take the initiative by supporting ongoing innovation

Agile go-to-market methods were essential for success when the burgeoning biosimilars market was examined in 2021. As new biosimilars enter the market, businesses must constantly modify their market positioning and strategy to account for the altering competition landscape. Effective commercial strategies, it is thought, strike a balance between three competing imperatives: increasing savings for payers and providers through incentives; lowering the cost of the product for patients and improving tendering capabilities to secure volume gains; and tailoring pricing and channel strategies to specific products and nations to gain traction at the physician level.

In mature economies, the ability to balance business strategies across a variety of channels will be essential. To accomplish this, one must first develop a detailed grasp of the decision-making processes of physicians and patients, as well as the flow of funds at payers and providers, before leveraging that knowledge to segment these groups into various channels. This is a problem that requires constant attention. Companies will need to keep adjusting and fine-tuning their strategies in response to how stakeholders engage and how physicians and payers get more comfortable using biosimilars, partially as

a result of the disruptions caused by the COVID-19 pandemic.

Deep channel analytics will be required of pharma companies, along with the development and testing of numerous models and the search for contract partners. For instance, based on their needs in oncology, various countries might require different business approaches. Support for hospitals and statutory-health-insurance doctors for biosimilars may be developed in Germany through the use of multistakeholder platforms that include payers and providers. Manufacturers in the UK could work with "chemo at home" vendors and chemo compounding companies to coordinate delivery.

While waiting for outcome-based models to be created, for example in France, real-world evidence initiatives in both hospitals and primary-care settings may boost the confidence in prescribing biosimilars in the field of immunology. Since biologics are exclusively acquired and administered at hospitals in Spain, the pertinent models may be developed according to area and hospital size. In general, companies must forge strong local connections where they can and provide education to increase awareness in countries like China and Brazil where biosimilars haven't yet attracted the attention of many medical professionals.

The ability of biosimilars to offer cheaper costs is commonly credited with their success; nevertheless, companies must consider the situations in which discounting may be more significant than in their prelaunch market models.6 As a result, originator businesses are currently competing utilizing a range of tactics, like modified contractual terms. Variously successful, others have introduced their own biosimilars. For instance, when Darbepoetin AL KKF, a biosimilar to the original drug Nesp, was launched in Japan, it immediately outperformed the other three biosimilars by a ratio of 10, surpassing their market share.

The average launch discount for most biosimilars in the US was less than 10% of the typical sales price, with an average annual price decline of 10% to 15%. Businesses must think about how their strategy might alter if more biosimilars hit the market, particularly for conditions like chronic illnesses where there are more than five competing drugs. For instance, the arrival of up to eight adalimumab biosimilars in the United States in 2023 may result in distinct market dynamics.
Companies that produce biosimilars should think about the best technique and distribution plan for each medication in each market. Across channels, accounts, and formularies, many firms are likely to employ strategies and methods that are very dissimilar from one another.

Finally, pharma and biosimilars companies are under pressure more than creative medicine companies due to regulation-restricted access to healthcare providers. More volume share than before is being taken in Europe by newer biosimilars that are entering the market for new compounds that have not yet been introduced. Biosimilars enterprises need to make remote engagement a crucial part of their business model in order to minimize their cost of sales and boost physician involvement in order to be competitive and sustainable.

3.3 Portfolio management: Use a unique strategy and expand swiftly

The commercial lifecycle of biosimilars is shortening as new medication generations emerge to replace standards of care, forcing businesses to make hasty decisions about their upcoming wave of products. Biologic drugs worth approximately $170 billion will lose their patent protection between now and 2030. More than 45 of these compounds report annual sales in the billions of dollars. On the opposite end of the scale, several biologics with far lower annual volumes—less than 500 kg—have off-patent blockbuster biologics that frequently record annual quantities of more than 1,000 kg.

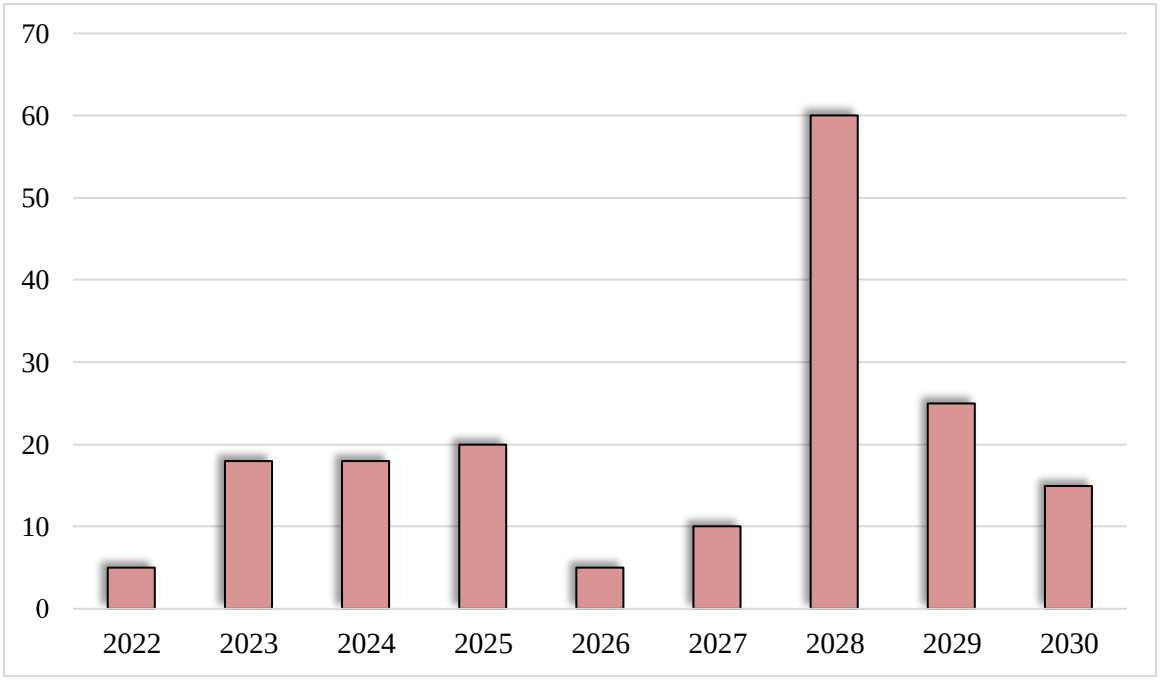

Fig 1.7: Cumulative peak sales of blockbuster brands that lose exclusivity, $ Billion

Given that production scale effects technology choice, unit cost, and cost of goods sold, such significant disparities suggest a diversified approach to portfolio management. Along with more traditional factors like the therapeutic area, revenue size, portfolio synergies, number of candidate products, development sequencing, geographic scenarios, and competition monitoring, production volume will need to be considered as an extra consideration in decision-making.

Another crucial aspect of portfolio management is the complexity of the industrial and medical industries. When several products are being developed at the same time, there are more trials, sites, patients to track, and personnel to organize. Only companies with strong internal R&D departments or those that work closely with contract research organizations and strategic partners will probably be able to manage a broad portfolio. A wider range and lower volume per drug make it more challenging to manage transitions from one molecule to another. This could lead to one production line instead of the usual one or two being shared by four or more molecules.

Along with choosing the finest goods for their portfolio, companies need to use more flexible and innovative pricing and contracting strategies, such as performance- and indication-based methods. Another way for firms to differentiate themselves from the competition and narrow in on a specific specialization adopt cutting-edge manufacturing techniques, like modular factories created for low-volume production. (Olech, 2016)

3.4 R&D: Quicken development and cut expenses

Companies must accelerate the development of their medicines if they want to put biosimilars first to market. According to a survey of seven biosimilars launched in Europe, the three best-selling biosimilars for a variety of compounds tend to be early entrants and account for more than 90% of the market between them.

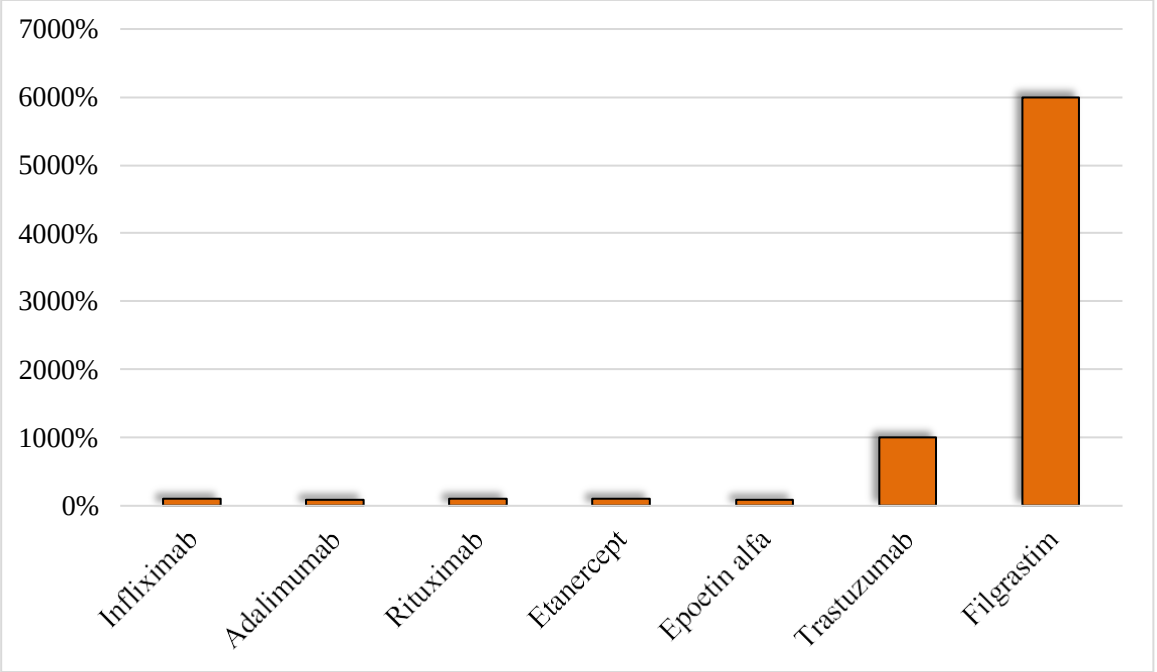

Fig 1.8: Market share of biosimilars in France, Italy, Germany, Spain, and the United Kingdom

To maintain sustainability in interim, biosimilars business must cut costs, notably in medication development. Currently, the cost to develop a typical biosimilar ranges from $100 million to $300 million, with clinical studies taking up the majority of the expense. Companies could modify their development plans to scale back clinical trials in order to save money. In its 2019 draft guidance on creating biosimilars and interchangeable insulin products, the FDA followed suit. The European Medicines Agency proposed the possibility of exempting insulin biosimilars from immunogenicity testing in certain situations in 2015. (Kirchoff, 2017)

To assist minimize the remaining uncertainties that require human trials for novel biosimilars, companies wanting to adopt lean models for producing biosimilars may also turn to rapidly evolving technology like data platforms and data analytics.

3.5 Current status of the Indian market

India, in contrast to other countries, has a thriving biosimilar ecosystem, and as a result, Indian pharmaceutical firms have risen to the top of the global market for biosimilars. India gave the green light to its first biosimilar a lot sooner than the US and EU did. In India, the first biosimilar was licensed and put on the market for hepatitis B in 2000, despite the lack of defined standards at the time for its development and marketing. Since then, other biopharmaceutical companies have created and launched

biosimilars in India. A recent USFDA approval for the marketing of a new biologic was received by an Indian biopharmaceutical company.

India's FDA approved first biologic is Herceptin, treatment for some types of stomach and breast cancer. Herceptin's active ingredient is trastuzumab. Additionally, this was the first comparable biologics produced by an Indian business to be given permission to be marketed in the US.
There are already more than 100 Indian biopharmaceutical businesses involved in the production and promotion of biosimilars. (Patel, 2015)

Product Name	**Active Drug**	**Indication**
Glaritus	Insulin glargine	Diabetes mellitus
Grafeel	Filgrastim	Neutropenia
Epofer	Epoetin Alfa	Anemia
Krabeva	Bevacizumab	Colorectal cancer
Herceptin	Trastuzumab	Breast Cancer
Abcixirel	Abciximab	Autoimmune disease
Relibeta	Interferon beta-1a	Multiple sclerosis
Intacept	Etanercept	Rheumatoid Arthritis

Table 1.3: List of some biosimilars approved in India

Conclusion

Biosimilars have the potential to improve patient accessibility for a variety of malignant and nonmalignant illnesses by reducing the cost of care. Creation and application of "biosimilars or similar biologics" have expanded significantly since the first biosimilar was used. Regulatory organizations regularly approve several biologics that are identical to one another for the treatment of numerous malignant and non-cancerous diseases. India is a major player on the international stage in the production of comparable biologics. Due to its growing population, it is also a sizable market for biologics similar to those mentioned above. Although India has great potential and tremendous expectations, maintaining the top spot will provide massive and difficult obstacles.

The biosimilars market is a thriving one, growing quickly and having a significant impact on the healthcare system. The pace can only quicken as the US quickens its biosimilars trip, a new batch of compounds lose their exclusivity, and regulatory and market structure shift. Businesses may launch more biosimilars more quickly by improving the commercial model, shortening time to market, managing portfolios, and lowering development costs. Growing demand for biosimilars may lead to lower healthcare costs and more patients having access to cutting-edge therapies at more reasonable pricing. Payers and providers may use the savings to raise the standard of care for all patients.

Even while health policies in other countries have been developed and put into practice under conditions that are different from those in the U.S., there are numerous opportunities for the U.S. to gain from their experiences with policies that have advanced the use of biosimilars. Both European and American biosimilar legislation aim to reduce the cost of effective biologics after the original product's exclusivity term has ended while guaranteeing that the affordable biologics have no significant clinical differences. Biosimilars are being used increasingly often in European markets, with no signs of uncommon or unexpected adverse events or indications of differences in efficacy between biosimilars and their reference biologics.

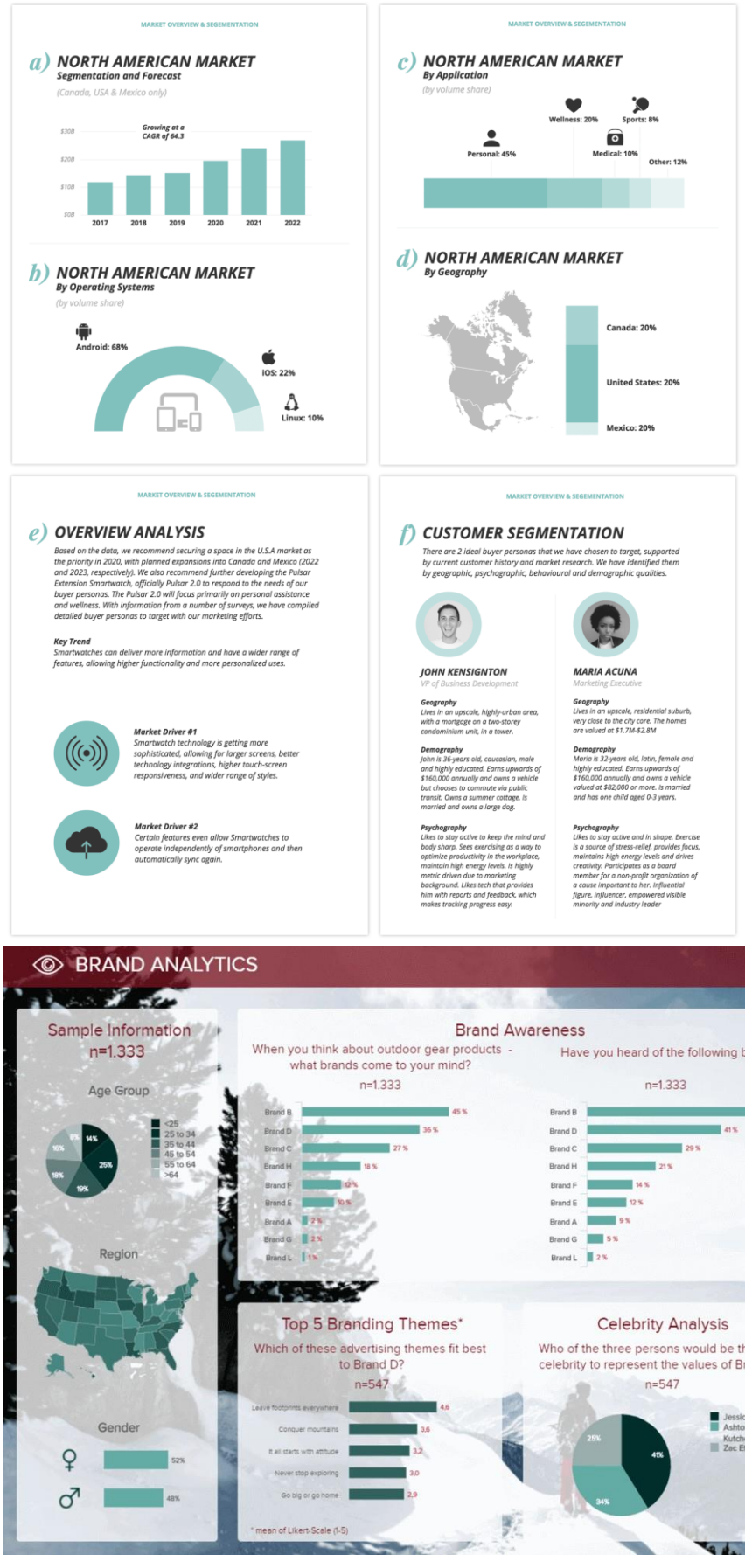

Fig 1.7: Template of a research report

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