Prague University of Economics and Business

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THE USE OF TECHNOLOGY INTELLIGENCE PROCESSES IN THE MANAGEMENT OF RESEARCH AND PRODUCTION OF NEW DRUGS

MASTER THESIS

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Abstract

Abstrakt v Českém jazyce

Tato diplomová práce se věnuje procesům Technology Intelligence pro oblast zdravotnictví se zaměřením na analýzu patentových dokumentů a nepatentové literatury. Analýza je zaměřena na tři modelové skupiny léčiv. První je skupina léčiv velmi dobře prozkoumané oblasti poruch funkce štítné žlázy, které se manifestují jako výsledná snížená funkce (hypotyreóza) a jsou ovlivnitelné léčivy zaměřenými na substituci hormonu štítné žlázy. Druhá modelová skupina ilustruje situaci antiflogistických a analgetických léků, které nejsou regulovány a jsou volně dostupné. Jako třetí modelová skupina je představena skupina protinádorových léků vyvíjených na podkladě znalosti molekulární a genetické podstaty nádorových onemocnění. V této skupině jsou k dispozici nové léky ovlivňující hlavní regulační body buněčných regulačních cest, jejichž poruchy jsou podkladem vzniku nádorových onemocnění. Podobně jako výzkum endokrinních poruch popsaných v první modelové skupině, tato nová léčiva umožňují ovlivnění geneticky různorodých poruch shodnými léky a to proto, že ovlivňují příslušnou regulační cestu, která je obecně shodná. Srovnání modelových skupin léků umožňuje odhadovat nové strategie výzkumu a výroby léků. Diplomová práce je rozdělena na čtyři části, v první části práce popisuje životní cyklus Technology Intelligence se zaměřením na možné využití v oblasti farmacie. Druhá část představuje konkrétní vstupy TI na základě definovaných Key Technology Intelligence Questions, určené informační zdroje, analytické metody a reporting. Třetí část prakticky demonstruje celý proces TI včetně postupu získávání dat a informací, přípravy množiny klíčových slov, rešeršní strategie a vyhodnocení relevance výsledků na výše uvedených skupinách léčiv. Čtvrtá část je syntézou získaných výsledků se závěrečnou diskusí.

Abstract in English

This thesis is focused on Technology Intelligence processes for the healthcare sector with an emphasis on the analysis of patent documents and non-patent literature. The analysis is focused on three model groups of pharmaceutical drugs. The first group comprises medications from a very well-researched area of thyroid gland disorders that manifest as a resulting decreased function (hypothyroidism) and are influenced by medicaments targeting the substitution of the thyroid hormone. The second model group illustrates the situation of non-steroidal anti-inflammatory drugs and analgesics that are not regulated and are freely available. The third model group is represented by a group of anticancer drugs developed based on the knowledge of the molecular and genetic nature of cancer diseases. In this group, new drugs are available that influence the main regulatory points of cellular regulatory pathways, the disorders of which are the basis for the development of cancer diseases. Similarly to the research of endocrine disorders described in the first model group, these new drugs allow for the influence of genetically diverse disorders by the same drugs because they affect the respective regulatory pathway that is generally the same. The comparison of model groups of drugs allows for the estimation of new research and drug production strategies. The thesis is divided into four parts, the first part describes the Technology Intelligence life cycle with a focus on possible applications in the pharmaceutical industry. The second part presents the specific TI inputs based on the

defined Key Technology Intelligence Questions, information sources, analytical methods, and reporting. The third part practically demonstrates the entire TI process, including the data and information acquisition process, the preparation of a set of keywords, research strategy, and evaluation of the relevance of results on the above-mentioned groups of drugs. The fourth part is a synthesis of the acquired results with a final discussion.

Keywords

Technology Intelligence, pharmaceuticals, hypothyroidism, NSAIDs, analgesics, cancer treatment

Content

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List of Abbreviations

ATC	Anatomical Therapeutic Chemical
AU	Australia
CA	Canada
CZSO	Czech Statistical Office
DDD	Defined Daily Dose
DSR	Design Science Research
EP	European Patent
EPC	European Patent Convention
EPO	European Patent Office
FIS	Faculty of Informatics and Statistics
INID	International Numbering for Identification of Data
IPC	International Patent Classification
KIT	Key Intelligence Topic
KIQ	Key Intelligence Question
KIQ1MG1	Key Intelligence Question 1 for Model group 1
MeSH	Medical Subject Headings
MG	Model Group
MT	Master Thesis
NCBI	National Center for Biotechnology Information (NCBI)
NIH	National Institutes of Health (NIH) in the United States
NLM	National Library of Medicine
NSAIDs	Non-steroidal anti-inflammatory drugs
PCT	Patent Cooperation Treaty
SUKL	Státní ústav pro kontrolu léčiv
R&D	Research and development

T3	Triiodothyronine
T4	Thyroxine
TI	Technology Intelligence
USPTO	The United States Patent and Trademark Office
WIPO	World Intellectual Property Organization
WHO	World Health Organization
WHOCC	World Health Organization Collaborating Centre for Drug Statistics Methodology
WO	World Intellectual Property Organization international patent
WoS	Web of Science

1 Introduction

Technology intelligence (TI) is an increasingly important business practice ensuring the necessary advantages companies need to distinguish the opportunities and threats that could potentially influence their business. It can be defined as pertaining to “business-sensitive information about external scientific or technological developments that can affect a company’s competitive position” and being a “structured process that includes four important steps”: Planning, collecting, analyzing, and disseminating (Parry, 2000). Technology intelligence is a subfield of competitive intelligence, which is the process of gathering and analyzing information about competitors and the market to gain a competitive advantage. TI specifically focuses on collecting and examining information about technology trends, developments, and innovations, with the goal of staying ahead of the competition and making informed decisions about technology-related investments and strategy.

TI involves several key activities, including monitoring technology news and developments, conducting research on emerging technologies, and analyzing the potential impact of new technologies on an organization's operations and competitive position. This information can then be used to inform decision-making, such as identifying new technologies to invest in, developing strategies for leveraging technology to gain a competitive advantage, and identifying potential threats and opportunities related to technology.

This Master Thesis (MT) focuses on technology intelligence processes for the healthcare sector, with an emphasis on the analysis of patent documents and non-patent literature. The research is divided into three model groups of pharmaceutical drugs: medications for reduced function thyroid gland disorders, non-steroidal anti-inflammatory drugs and analgesics, and anticancer drugs. The work is divided into four parts: the first part describes the TI life cycle and its potential applications in the pharmaceutical industry, the second part subsequent section provides a comprehensive analysis of patent documents, including a detailed explanation of the application process, including its Process map diagram depiction, the third part presents the specific TI inputs based on defined key questions and information sources and then demonstrates the technology intelligence process on the three model groups, and the fourth part is a synthesis of the results with a final discussion.

There are several medications available for the treatment of thyroid gland disorders. These medications can be divided into two main categories: those that are used to treat an underactive thyroid gland (hypothyroidism), and those that are used to treat an overactive thyroid gland (hyperthyroidism). For hypothyroidism, the most commonly prescribed medications are synthetic thyroid hormones, such as levothyroxine. These medications are designed to replace the missing thyroid hormones in the body and can help to restore normal thyroid function. For hyperthyroidism, commonly prescribed medications are antithyroid drugs, such as propylthiouracil and methimazole. These medications work by

blocking the production of thyroid hormones and can help to reduce the symptoms of hyperthyroidism. In some cases, radioactive iodine may also be used to treat hyperthyroidism. This treatment involves taking a small dose of radioactive iodine, which is absorbed by the thyroid gland and destroys the cells that produce thyroid hormones. This can help to reduce the production of thyroid hormones and alleviate the symptoms of hyperthyroidism. In addition to medications, there are several other treatments available for thyroid disorders. These treatments can be used alone or in combination with medications, depending on the specific type and severity of the disorder. Another treatment option for thyroid disorders is surgery. This can involve removing all or part of the thyroid gland, depending on the specific condition, which can be an effective treatment for certain types of thyroid cancer, as well as for certain types of hyperthyroidism. However, this study will only investigate treatments of hypothyroidism.

The second group encloses non-steroidal anti-inflammatory drugs (NSAIDs), which are a type of medication that is commonly used to reduce inflammation and relieve pain. They work by blocking the production of prostaglandins, which are chemicals that are involved in the inflammation and pain process. NSAIDs are available over the counter or by prescription and can be taken orally or applied topically to the skin. Common NSAIDs include ibuprofen, diclofenac, and naproxen. Analgesics, also known as painkillers, are medications that are used to relieve pain. They work by blocking pain signals from being sent to the brain, or by interfering with the brain's perception of pain. Analgesics can be divided into two main categories: non-opioid analgesics, which include medications like paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs), and opioid analgesics, which are stronger painkillers that are typically only prescribed for severe pain.

There are many different types of anticancer drugs that have been developed based on our understanding of the molecular and genetic basis of cancer. These drugs are designed to target specific molecular and genetic abnormalities that are associated with the development and progression of cancer. One group of anticancer drugs that have been developed on this basis are targeted therapies. These drugs are designed to target specific molecules or pathways that are involved in the development and growth of cancer cells. Examples of targeted therapies include monoclonal antibodies, which are proteins that specifically target and bind to molecules on the surface of cancer cells, and tyrosine kinase inhibitors, which are drugs that block the activity of enzymes called tyrosine kinases that are involved in signaling pathways that promote cancer cell growth and survival. Another group of anticancer drugs that have been developed based on our understanding of the molecular and genetic basis of cancer are immunotherapies. These drugs are designed to boost the body's immune system so that it can more effectively recognize and attack cancer cells. Examples of immunotherapies include checkpoint inhibitors, which are drugs that block molecules on immune cells that cancer cells use to evade the immune system, and cancer vaccines, which are vaccines that are designed to stimulate the immune system to recognize and attack cancer cells.

The reason for the selection of the analyzed groups of pharmaceutical drugs is as follows. Contemporary medications of thyroid gland disorders and disorders based on impaired mechanisms of the function of thyroid hormone are a result of a century long endocrine research in this field. These medications are very effective in the treatment and

medication of a relatively large set of mechanistically distinct disorders. The second group of pharmaceuticals represent pharmaceutical treatment of medical symptoms (pain and inflammation) that can be effectively controlled by patients themselves. The justification for this is the wide regulatory network that is involved in perception of pain and inflammatory processes. The extent of regulatory processes and their individual involvement in the particular patient (user) makes these drugs suitable for open purchasing as well as in the field of pharmaceutical research that find new drugs for this medical purpose. The third group of drugs (anti-cancer pharmaceuticals) illustrates the contemporary state of the art in the group of diseases (genetic disorders leading to malignancies) that constitute a large set of distinct disorders. Focused research led to the discovery of effective pharmaceutical interventions that can effectively treat even genetically different disorders based on affecting shared biological regulations which impairment is to a large extent shared between different types of malignancies. As a subgroup of the anticancer strategies there is the emerging employment of genetically modified T lymphocytes of patients in order to shift their biological regulatory potential against the cancer cells regardless of the particular genetic disorder. In this sense, it can be anticipated that similarly as in the first group of treatment of thyroid hormone related disorders, the contemporary strategies of the treatment of malignancies are likely to result in effective treatment and cure of cancers.

1.1 Aims and objectives

The main objective is to propose a procedure for the use of patent and non-patent information entities for the field of Technology Intelligence with primary use for analysis of the external environment of pharmaceutical companies and organizations, as well as identify trends in selected drug sectors, while considering only open data.

In order to achieve the defined goal, the following sub-goals with their own research questions have been selected:

1. Identify and classify relevant patent and non-patent information entities for the field of Technology Intelligence within the three model groups. Research question: What are the most relevant patent and non-patent information entities for technology intelligence in the pharmaceutical industry?

2. Develop a procedure for the collection and analysis of the identified information entities using open data sources. Research question: How can open data sources be effectively used to collect and analyze relevant patent and non-patent information entities for technology intelligence in the pharmaceutical industry within the selected groups?

3. Identify trends in selected drug sectors using the collected and analyzed information. Research question: What are the current trends in selected drug sectors as identified through the analysis of relevant patent and non-patent information entities using open data sources?

4. Evaluate the effectiveness of the proposed procedure for technology intelligence analysis in the pharmaceutical industry. Research question: How effective is the proposed procedure for technology intelligence analysis in the pharmaceutical industry as evaluated through the identification of trends in selected drug sectors?

1.2 Methodology

The Design Science Research (DSR) methodology is a framework for conducting research that aims to solve practical problems and create new knowledge in the field of design. This approach focuses on creating solutions to real-world problems and evaluating their effectiveness, rather than just generating theories or abstract concepts. The DSR process typically begins with a thorough review of the existing literature on the topic, followed by the identification of a specific problem or opportunity. The next step is to develop a solution to the problem, which may involve creating a new design, model, or framework. This solution is then tested and refined through a series of experiments, simulations, or other forms of evaluation.

One key aspect of the design science methodology is the emphasis on creating artifacts that can be used in the real world. These artifacts could be anything from a new product or service to a design tool or framework. The goal is to create something that has tangible value and can be used to address the identified problem. Another important aspect of design science research is the use of rigorous evaluation methods to assess the effectiveness of the proposed solution. This may involve collecting data through experiments, surveys, or other methods, and analyzing the results to determine whether the solution is effective and useful.

Overall, the DSR methodology is a systematic and meticulous approach to creating solutions to real-world problems and evaluating their effectiveness in addressing those problems. By focusing on the creation of tangible artifacts and the use of thorough evaluation methods, this approach seeks to generate new knowledge and insights that can be applied in practical settings. Comparing the earlier mentioned three groups of pharmaceuticals allows estimating how research and practice in the field of symptom-fighting drugs, which may be mostly available, and in the field of anti-tumor treatment, which is so specialized that it must be managed at the national level, can develop.

The use of technology intelligence on the aforementioned groups of drugs will lead to the formation of the objective of this work, which is a procedure that can be applied to other drug groups.

1.3 Current State of Research and Information Sources

At the time of writing this thesis, there were no works on the same topic concerning the pharmaceutical industry with the focus on model groups of drugs. There were works with general case studies (regarding for example the automobile industry and optics as in the case of the dissertation *Competitive Technical Intelligence* by PhDr. Jan Černý, Ph.D.)

and Competitive Intelligence themed papers focused on social networking, broad-spectrum business in a certain country, or works comparing small and large businesses. This thesis takes insight from Černý's dissertation in terms of its approach to patent documents. Other works concerning TI were consulted, such as *Competitive Technical Intelligence: A Guide to Design, Analysis and Action* (Coburn, 1999).

This thesis focuses on Technology Intelligence processes with an emphasis on the analysis of patent documents and non-patent literature. The work *Using Competitive Technological Intelligence Patent Search Methods to Uncover Automotive Industry Trends* (Molnár, Černý, 2017) was used for inspiration. To get an understanding of the available drugs for each model group within the case study, the SUKL website was investigated. SUKL stands for State Institute for Drug Control in the Czech Republic. It is a government agency responsible for the regulation of medicinal products in the Czech Republic. Its main tasks include the evaluation of the quality, safety, and efficacy of medicinal products, the registration and marketing authorization of medicinal products, the monitoring of the adverse effects of medicinal products, and the inspection of pharmaceutical companies and pharmacies. SUKL also provides information and education to healthcare professionals and the general public about medicinal products.

To evaluate patent documents PatentScope was utilized. PatentScope is a free, online patent database maintained by the World Intellectual Property Organization (WIPO). PatentScope allows users to look for patent documents using a variety of search criteria, such as keywords, inventors, and patent classifications and provides machine translation capabilities for patent documents in various languages. In addition to search and retrieval, PatentScope also offers other useful features, such as patent family and legal status information, which can help users understand the scope and status of a patent application or granted patent. PatentScope is a valuable resource to access patent information. Furthermore, literature on patent searching (Hunt,2007) and pharmaceutical competitive intelligence (Huml, 2012) were consulted.

To easily identify and compare drugs based on their pharmacological properties and therapeutic uses, the Anatomical Therapeutic Chemical (ATC) classification system was consulted for a standardized method for identifying and categorizing drugs. It is maintained by the World Health Organization (WHO) and is used to classify and identify drugs according to their therapeutic use and chemical composition. The ATC code is a seven-character code that consists of five different levels of classification:

1. Anatomical main group: This is the first level of the ATC code, and it classifies drugs according to the main anatomical system or organ on which they act.
2. Therapeutic subgroup: This is the second level of the ATC code, and it further classifies drugs according to their therapeutic use.
3. Pharmacological subgroup: This is the third level of the ATC code, and it classifies drugs according to their mode of action or pharmacological properties.
4. Chemical subgroup: This is the fourth level of the ATC code, and it classifies drugs according to their chemical structure.
5. Chemical substance: This is the fifth level of the ATC code, and it identifies the specific drug or active ingredient.

Information about this classification system can be found on the official website of the World Health Organization Collaborating Centre for Drug Statistics Methodology (WHOCC), which maintains the ATC classification system and the Defined Daily Dose (DDD) methodology for drug utilization research. The ATC code is used worldwide for drug utilization studies, drug reimbursement, and other purposes related to drug monitoring and regulation. The code provides a standardized way of identifying and comparing drugs, regardless of their brand or generic names, and enables healthcare professionals and regulators to monitor and evaluate drug use and safety across different populations and countries (WHO, 2023).

Other important documents were obtained from PubMed and PubChem. PubMed is a free online database that provides access to millions of citations and abstracts from biomedical literature, including articles, books, and research reports. It is maintained by the National Institutes of Health (NIH) in the United States and is a primary resource for information in the fields of medicine, nursing, dentistry, veterinary medicine, and the preclinical sciences. PubChem is a public database maintained by the National Center for Biotechnology Information (NCBI), which is part of the NIH in the United States. It is a freely available resource that provides information on the properties and activities of millions of chemical compounds, including small molecules, drugs, and natural products. PubChem contains three main databases: Substance, Compound and BioAssays. The substance database contains information on chemical substances, including their chemical structures, names, and identifiers. The Compound database contains information on individual chemical compounds, including their physical and chemical properties, biological activities, and references to scientific literature. The BioAssay database contains information on the biological activities of chemical compounds, including data from high-throughput screening assays, which are used to identify compounds that have potential therapeutic or biotechnological uses.

Furthermore, Scopus and Web of Science were used to find and access scholarly literature. Scopus is a bibliographic database that indexes and abstracts research literature from peer-reviewed journals, books, and conference proceedings. It covers a wide range of subject areas, including science, technology, medicine, social sciences, and arts and humanities. Scopus is owned by Elsevier, a publishing company, and provides access to citation data, h-index, and other metrics that help researchers assess the impact of their work. Web of Science (WoS) is a similar database that indexes and abstracts research literature from scholarly journals, conference proceedings, and books. It also covers a range of subject areas, including science, technology, social sciences, and arts and humanities. Web of Science is owned by Clarivate Analytics and provides access to citation data, journal impact factor, and other metrics.

2 Technology Intelligence

Technology intelligence is the process of collecting, analyzing, and disseminating information about the technology-related activities of competitors and other organizations. The goal of TI is to help understand and anticipate the technological capabilities and plans of competitors, and to make informed decisions about technology development and deployment. There are various approaches and methods:

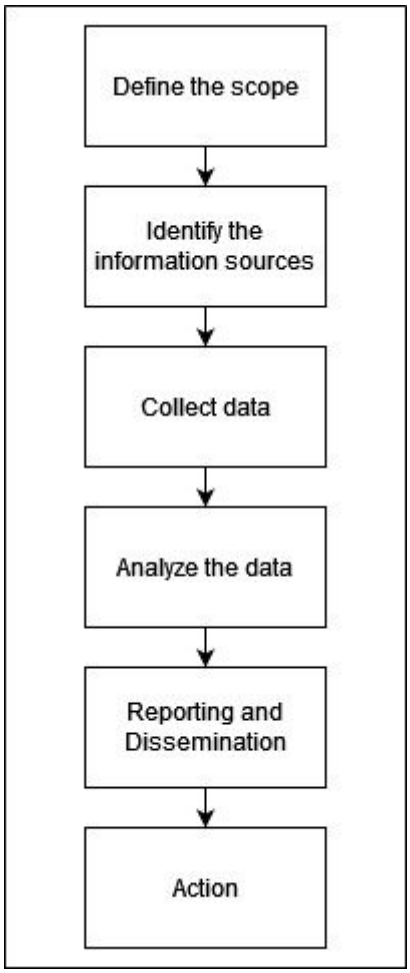

Figure 1 TI steps, by the Author

Patent analysis: Examining patents and patent applications filed by competitors to identify their technological areas of focus and potential innovations.

Literature review: Searching scientific and technical literature for information about the research and development activities of competitors.

Market analysis: Analyzing market trends and data to identify potential technological opportunities and threats.

Social media and web scraping: Using tools to monitor and analyze online discussions, blogs, and other social media sources for information about competitors' technology-related activities.

Interactions with customers, suppliers, and other stakeholders: Talking to customers, suppliers, and other stakeholders to gather insights about competitors' technology-related plans and activities.

Attendance at conferences and trade shows: Attending conferences and trade shows to learn about new technologies and developments in the industry.

This work will utilize the analysis of patent documents and non-patent literature.

2.1 Definition of terms and the theoretical framework of TI

This section provides definitions for key terms and concepts used throughout this work. It serves to ensure a common understanding among readers and to avoid confusion or misinterpretation of the author's intended meanings and outlines the foundational theories, models, or perspectives that inform the author's analysis or argument. It establishes the theoretical lens through which the author examines the topic and provides a basis for understanding the significance and relevance of the author's work.

As stated by Černý in his dissertation, the TI process "is based on the principles of CI methods, and its life cycle is defined by four basic phases: 1) the formulation of needs, 2) data collection, 3) analysis, and 4) decision-making/action, with technology being a common denominator for these phases" (Černý, 2014: p25).[1] Correspondingly, according to Coburn, there are three fundamental components of competitive technical intelligence activity: data collection, data analysis, and action (Coburn, 10). Data collection provides the foundation of a complete story, data analysis brings insight, making a consistent story and putting the pieces of the puzzle together, while action is the natural outcome from the analysis. Additionally, Coburn warns that the abundance of data can hinder this entire process, stressing that "design starts with a good understanding of the purpose of the study (Coburn, 11)," thus confirming Černý's first step. In the absence of comprehension, one may tend to gather excessive information and may even overlook some pertinent information. This work will follow the phases of the TI lifecycle outlined by Černý, including the formulation of needs, data collection, and analysis, but the last step will be altered to provide recommendations rather than taking action, as the purpose of this work is not aimed at or cooperating with a specific company or organization.

In the relevant literature, TI is often referred to as Competitive Technology Intelligence (CTI) or interchangeably Competitive Technical Intelligence, in some literature even just Competitive Intelligence (CI), however, in this work, both CTIs will be unified from here on into the term Technology Intelligence (TI) and Competitive Intelligence (CI) will be taken as a broader concept that encompasses TI as a subset.

Pharmaceutical CI is the process of defining, gathering, analyzing, and distributing intelligence on pharmaceutical products, customers, and competitors (Huml, 2012). The process aids managers and executives in formulating strategic decisions for their organization. The products in question refer to drugs, devices, and biologics, while customers include pharmaceutical companies, contract research organizations,

[1] Translated by the Author from the Czech original: "Lze konstatovat, že proces CTI vychází z principů metod CI, jeho životní cyklus je definován čtyřmi základními fázemi: 1) formulace potřeb, 2) sběr dat, 3) analýza a 4) rozhodování/akce, přičemž společným jmenovatelem těchto fází jsou technologie."

pharmaceutical manufacturers, investors, patients, health payers, and even government organizations, in addition, the competitive landscape may be influenced by factors such as regulations, lack of regulations, long-awaited draft, politics, accounting principles, geographies, patent protection, and regulatory exclusivity (Huml, 2012). Huml goes on to explain the motivation behind performing CI, reasoning that while the key motive for acquiring CI information is making "the organization more competitive relative to its entire environment" (Huml, 2012: 2), it is necessary for there to be a decision-making element. This element is critical for ensuring that the insights and recommendations generated through CI are effectively utilized to achieve the desired outcomes. Nevertheless, in the case study of this work, this step will be altered, as previously mentioned above, due to not being targeted for a specific client.

2.2 TI and the process of identifying requirements

In the section, the context of Technology Intelligence (TI), its significance within the pharmaceutical sector, the process of formulating requirements and data collection, the specification of relevant data and the techniques to locate it, will be addressed along with the research strategy to be employed.

2.2.1 Context of TI and the pharmaceutical industry

CI is the process of gathering and analyzing information about the competition to support business decision-making. As mentioned, TI is a specific subset of CI that focuses on gathering and analyzing information about the technological capabilities and innovations of competitors. The context of TI within CI is that it provides crucial insights into the technological landscape of the industry as well as the potential threats and opportunities that could arise from competitor innovations. By gathering and analyzing information about the technological capabilities and innovations of competitors, companies can make informed decisions about their own technology development, product strategy, and overall business strategy.

TI involves a range of activities, including monitoring competitor patents, tracking new product releases, analyzing Research and Development (R&D) investments, and identifying emerging technological trends. By using this information, companies can recognize potential threats to their own products and services, assess the impact of competitor innovations on the industry, and identify potential opportunities for new product development or strategic partnerships.

In the pharmaceutical industry, TI plays a crucial role in identifying and tracking emerging technologies, evaluating their potential impact, and anticipating competitive threats and opportunities. Pharmaceutical companies face intense competition from other firms in the industry, as well as from generic drug manufacturers. They also operate in a

highly regulated environment that demands significant investment in research and development to bring new drugs to market (Huml, 2012). In this context, TI can provide valuable insights into the latest advances in drug development, clinical trials, and regulatory requirements, enabling companies to stay ahead of the competition.

Specific applications of TI in the pharmaceutical industry include: Identifying emerging technologies (to help companies prioritize their R&D efforts and investments), monitoring competitor activities (companies can track the activities of their competitors, such as their drug development pipelines, licensing agreements, and acquisitions, to help companies anticipate competitive threats and opportunities), evaluating partnerships and collaborations (to help companies identify opportunities for technology transfer and collaborative research), and understanding regulatory requirements (providing insights into the latest regulatory requirements and guidelines, enabling to ensure compliance and avoid costly mistakes).

Overall, TI is a critical tool for pharmaceutical companies seeking to stay ahead in a highly competitive and rapidly changing industry. By providing timely and accurate information on emerging technologies, competitive threats, and regulatory requirements, TI helps companies make informed decisions that can drive their success.

2.2.2 Formulation of requirements and the research strategy

The Formulation of requirements and the research strategy for this MT involved identifying the key objectives of the project and defining the scope of the research. After deciding on the specific model groups of pharmaceuticals explored within this study, the TI lifecycle was followed, a detailed description of the TI implementation can be found in Chapter 4 (TI Implementation proposal) and is carried out in Chapter 5 (Case Study) on three groups of drugs, to investigate the effectiveness of the TI procedure concerning data of the pharmaceutical industry. The study focuses on the three groups of drugs and aims to identify relevant patent and non-patent information entities, develop a procedure for their collection and analysis, identify trends in selected drug sectors, and evaluate the proposed procedure's effectiveness, with regards to the research questions of this MT.

The first research goal is to identify and classify relevant patent and non-patent information entities for technology intelligence in the pharmaceutical industry within the selected groups of drugs. The research question guiding this goal is: What are the most relevant patent and non-patent information entities for technology intelligence in the pharmaceutical industry? The second research goal is to develop a procedure for the collection and analysis of identified patent and non-patent information entities using open data sources. The research question guiding this goal is: How can open data sources be effectively used to collect and analyze relevant patent and non-patent information entities for technology intelligence in the pharmaceutical industry within the selected groups? The third research goal is to identify trends in selected drug sectors using the collected and analyzed information entities. The research question guiding this goal is: What are the current trends in selected drug sectors as identified through the analysis of relevant patent

and non-patent information entities using open data sources? The final research goal is to evaluate the proposed procedure's effectiveness for technology intelligence analysis in the pharmaceutical industry. The research question guiding this goal is: How effective is the proposed procedure for technology intelligence analysis in the pharmaceutical industry as evaluated through the identification of trends in selected drug sectors?

This MT focuses on patent documents and non-patent literature, for that reason patents are explored in more detail in Chapter 3 (Patents). To analyze the pharmaceutical industry from external factors and to understand the competitive forces within this industry, PESTLE analysis and Porter's Five Forces were used in subchapter 2.4 (The Pharmaceutical industry). The Case study in Chapter 5 then showcases the TI process on real data with the formulation of requirements, data collection relevant to the research objectives, and analyses of results.

2.3 Technology road mapping

In this section, technology road mapping will be explained. Technology road mapping is a strategic planning method used to align technological development with organizational goals and objectives. It provides a visual representation of technological developments and identifies the necessary steps and resources needed to achieve desired outcomes. It is "a flexible technique that is widely used within industry to support strategic and long-range planning. The approach provides a structured (and often graphical) means for exploring and communicating the relationships between evolving and developing markets, products and technologies over time" (Phaal, 2004: 5). According to Albright, roadmaps are used to define future objectives and address the questions "why-what-how-when," which are essential for developing an action plan (Albright, 2007). The process of technology road mapping in this work involves several steps: defining the scope, gathering data, identifying critical factors, creating the roadmap, and persistent reviewing and updating if needed.

These general steps can be described in more detail and applied to the pharmaceutical industry:

- Define the scope: The first step is to define the scope of the technology road mapping exercise. This involves identifying the technology areas, products, and services that will be included in the roadmap.

The pharmaceutical industry includes companies that research, develop, manufacture, and market drugs, vaccines, and other medical products for the prevention, treatment, and management of diseases and health conditions. The scope of the pharmaceutical industry also includes the various stages of the drug development process, from preclinical research to clinical trials to regulatory approval and commercialization. Additionally, the industry encompasses various therapeutic areas, such as oncology, cardiology, neurology, and infectious diseases, among others. The scope may also include related services, such as drug delivery systems, diagnostics, and medical devices. Therefore, the scope of the pharmaceutical industry is broad and encompasses various areas related to the research, development, and commercialization of medical products.

- Gather data: The next step is to gather data on the technology developments, market trends, and competitive landscape. This involves conducting a thorough analysis of the internal and external factors that impact the organization.

The following factors should be considered while gathering data regarding the pharmaceutical industry: research and development data, market trends including growth rates, market size and segmentation as well as trends in drug pricing, reimbursement and regulatory issues, an analysis of the competitive landscape including the major players, their market share and product pipelines, data regarding intellectual property (patent filings and grants, licensing agreements and litigation related to intellectual property), clinical trial information (ongoing and completed), healthcare policies related to drug approval, pricing but also related to drug safety, manufacturing and distribution, information pertaining to healthcare providers (hospitals, clinics and pharmacies, their role in drug selection, distribution and utilization), patient needs, preferences and behavior related to drug therapy and finally technology advancements (developments in drug delivery technologies, diagnostics and other related areas that could impact drug development and commercialization). This stage requires a comprehensive understanding of the industry's internal and external factors that impact drug research, development and commercialization.

- Identify critical technologies: Based on the data gathered, the critical technologies needed to achieve the organization's goals are identified. These may include emerging technologies, technologies that require significant investment, or those that have strategic importance.

The critical technologies in the pharmaceutical industry are those that have the potential to significantly impact drug discovery, development, and commercialization, as well as patient outcomes and healthcare delivery. These may include: gene editing and gene therapy, advanced drug delivery systems, artificial intelligence and machine learning, biologics and biosimilars, advanced analytics, digital health technologies such as wearables or mobile apps, even 3D printing.

- Create the roadmap: The roadmap is then created, which is a visual representation of the technology developments required to achieve the organization's goals. It includes timelines, milestones, and the necessary resources and activities needed to achieve the desired outcomes.

Different approaches can be taken towards creating a technology roadmap, one of which also focuses on patents. Lee recommended using patent analysis as a foundation for a technology-driven road mapping process that begins with capacity analysis and progresses to technological planning, business opportunity analysis, and market planning. Patents are according to Lee an excellent source of technical and commercial knowledge on technical advancements and innovative activities, thus they propose incorporating patent data as a parameter close to technological capacity. The integration of patent analysis into the road mapping process enhances objectivity and reliability, increases the extraction of strategic information, and assists in the decision-making process, resulting in greater benefits from expert opinions (Lee, 2009).

- Review and update: The technology roadmap is reviewed regularly to ensure it remains aligned with the organization's goals and objectives. It is updated as needed to reflect changes in the technology landscape, market trends, or internal priorities.

Technology road mapping can be conducted through a variety of methods, including workshops, surveys, interviews, and data analysis (Phaal, 2004). The process typically involves input from a range of stakeholders, including technology experts, business leaders, and customers. The roadmap is typically communicated throughout the organization to ensure everyone is aligned and working towards the same goals.

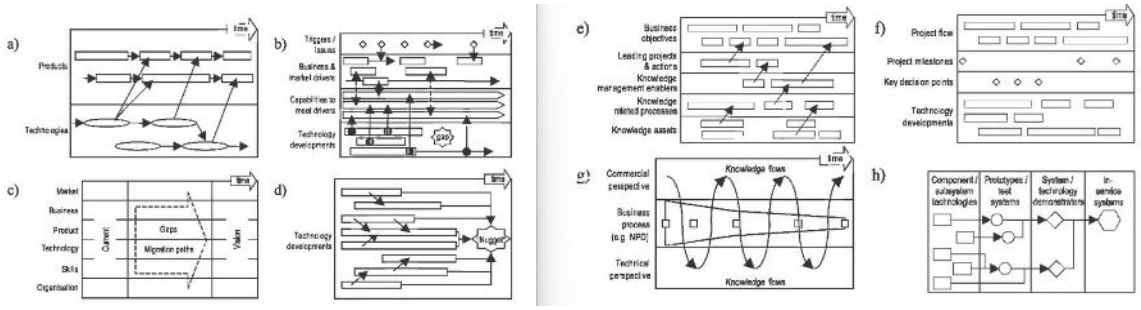

Figure 2 Examples of technology roadmap types (Phaal, 2003:12)

The following types of roadmaps were described by Phaal:

(a) Product planning: roadmap focused on the development and launch of new products or product lines.

(b) Service/capability planning: roadmap focused on the development and improvement of services or capabilities.

(c) Strategic planning: roadmap focused on the long-term strategic goals and objectives of the organization.

(d) Long-range planning: roadmap focused on long-term planning and forecasting, typically covering a period of 5-10 years or more.

(e) Knowledge asset planning: roadmap focused on the management and development of an organization's intellectual assets, including knowledge, expertise, and intellectual property.

(f) Program planning: roadmap focused on the planning and execution of a specific program or initiative.

(g) Process planning: roadmap focused on the improvement and optimization of internal processes and workflows.

(h) Integration planning: roadmap focused on the integration of different systems, processes, or capabilities to improve overall efficiency and effectiveness.

Based on the purpose of each technology roadmap type, knowledge asset planning would be the best for a patent analysis of the pharmaceutical industry. Knowledge asset planning (KAP) focuses on identifying and managing intellectual property, such as patents, trademarks, and copyrights, which are crucial for the pharmaceutical industry. By using knowledge asset planning, companies in the pharma industry can create a roadmap to identify and protect their intellectual property, as well as to leverage it to gain a competitive advantage. This could help them to manage their patent portfolio effectively and ensure that they are protecting their valuable inventions while maximizing their commercial value. The main goal of KAP is to identify, acquire, develop, protect, and leverage knowledge assets that are critical to the success of the organization. The KAP roadmap typically involves a comprehensive assessment of the organization's existing knowledge assets, as well as the identification of key areas where new knowledge assets need to be developed or acquired. The roadmap then outlines a plan for managing and leveraging these knowledge assets to achieve the organization's strategic goals. KAP is particularly relevant in industries such as pharmaceutical industry, where intellectual property and knowledge assets are critical to maintaining a competitive advantage.

To conduct KAP in the context of patent analysis in the pharmaceutical industry, the following steps could be taken:

Identify the relevant knowledge assets: In this step, the relevant knowledge assets for the patent analysis would be identified. These could include patents, scientific publications, clinical trial data, regulatory filings, and other relevant information sources.

Assess the value of the knowledge assets: The value of the identified knowledge assets would be assessed to determine their potential impact on innovation and competitiveness. This could be done by analyzing the quality, relevance, and applicability of the assets to the organization's strategic objectives.

Develop a knowledge management strategy: Based on the assessment of the value of the knowledge assets, a knowledge management strategy would be developed. This would involve determining how the knowledge assets would be captured, stored, shared, and leveraged to support innovation and competitiveness.

Establish metrics and targets: Metrics and targets would be established to measure the effectiveness of the knowledge management strategy. This could include metrics such as the number of patents filed, the number of scientific publications, and the impact of the knowledge assets on product development.

Implement and monitor the knowledge management strategy: The knowledge management strategy would be implemented and monitored to ensure that the desired outcomes are achieved. This would involve regular monitoring of the metrics and targets and making adjustments to the strategy as needed.

2.4 The pharmaceutical industry

Drug development, clinical trials, manufacturing, and distribution are essential phases in the pharmaceutical industry to bring new drugs to market and ensure their safe and effective delivery to patients.

Phases of the drug development can be discovery research (identifying new drug targets and developing new drug candidates through various methods, such as high-throughput screening, computer modeling, and natural product extraction), leading optimization (this involves refining and improving the properties of a drug candidate, such as its potency, selectivity, pharmacokinetics, and safety), pre-formulation (which involves testing and optimizing the physical and chemical properties of a drug candidate, such as its solubility, stability, and compatibility with different formulations), formulation development (designing and testing different formulations of a drug candidate, such as tablets, capsules, injections, or inhalers, to optimize its delivery and efficacy) and lastly patenting, to protect the intellectual property of the drug candidate and prevent others from copying or commercializing it without permission from the patent holder.

Clinical trials are a series of research studies conducted to determine the safety and effectiveness of a new drug or therapy. The clinical trial process involves the following steps: an exploratory study (the initial step where the researchers carry out laboratory tests and animal studies to determine if the new drug or therapy is safe and has the potential to be effective in treating the targeted condition), clinical trial design (researchers determine the number of participants needed for the trial and divide them into groups that receive different doses of the drug or a placebo), safety study (safety is a top priority, this step involves testing the drug's safety in humans, the researchers monitoring the participants for adverse reactions and side effects), efficacy and side effect study (assessing the effectiveness of the drug or therapy in treating the targeted condition, in this step the participants are monitored to see if the drug produces the desired effect and if it causes any side effects), large-scale testing (involves testing the drug or therapy on a larger group of participants to confirm its effectiveness and safety) and post-marketing surveillance: after the drug is approved by the regulatory authorities and is on the market, post-marketing surveillance is carried out to monitor any adverse effects or side effects that may arise during its use.

The steps involved in the manufacturing of a drug may include raw material sourcing, final formulation, process validation, scale-up and process development, production and packaging, quality control and release testing, and finally, distribution and logistics. Raw material sourcing involves sourcing and testing the raw materials needed for drug production, such as active pharmaceutical ingredients, excipients, and packaging materials. Final formulation encompasses the raw materials being combined in the appropriate quantities to create the final drug product. Then the manufacturing process is validated to ensure that it consistently produces a drug product that meets the required quality standards. Scale-up and process development ensures that once the process is validated, it can be scaled up to produce larger quantities of the drug. Process development involves optimizing the manufacturing process to improve efficiency, yield, and quality. Production and packaging is undergone so that the drug can be produced in large quantities,

and then the finished product can be packaged in the appropriate form, such as tablets, capsules, or injections. Quality control and release testing sees that quality control tests are performed to ensure that the drug meets the required specifications and standards for safety, efficacy, and purity. The drug product is then released for distribution. The finished drug product is shipped to distributors, wholesalers, and ultimately to pharmacies and healthcare providers for patient use. Proper distribution and logistics are critical to ensure that the drug is delivered safely and efficiently to its intended destination.

Distribution in the pharmaceutical industry involves the movement of drugs from the manufacturing site to the end users such as hospitals, pharmacies and other healthcare providers. This process typically involves several steps including warehousing and inventory management, transportation, order processing, supply chain management, cold chain management, and automated inventory and other management systems. Warehousing and inventory management involves the storage of drugs in a controlled environment with proper temperature and humidity levels to maintain their stability and potency. Transportation involves the movement of drugs from the manufacturing site to the warehouses and then to the end users, with the use of specialized vehicles equipped with temperature control and tracking systems. Order processing involves receiving and fulfilling orders from the end users, which may involve complex logistics and inventory management systems. Supply chain management ensures the timely and efficient movement of drugs throughout the distribution process, including procurement of raw materials and management of suppliers. Cold chain management is critical for drugs that require strict temperature control, such as vaccines and biologics, and involves the use of specialized equipment and procedures to maintain the appropriate temperature during transportation and storage. Automated inventory and other management systems use technology to optimize inventory management and logistics, including the use of barcode scanning, RFID, and other technologies to track and manage inventory levels, shipments, and deliveries.

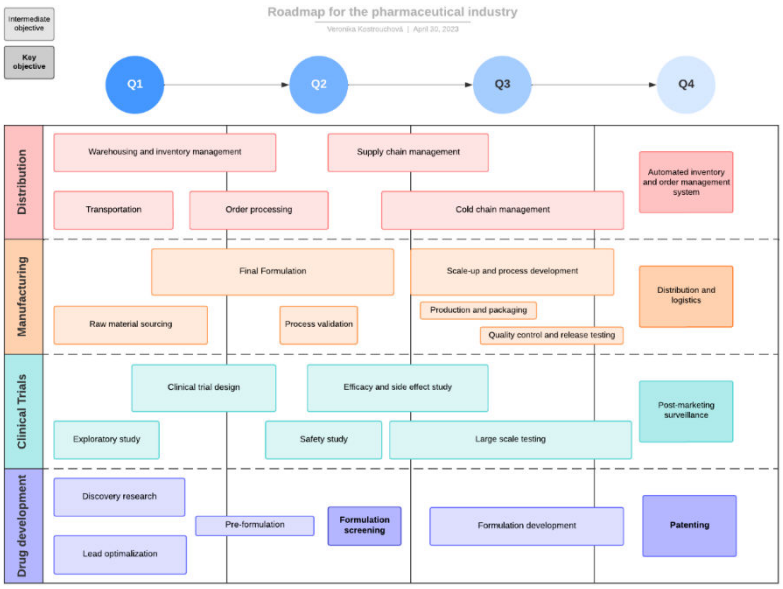

Figure 3 Overview of the phases, by the Author

When analyzing a business climate, it can be beneficial to look at the external environment or competitive forces within the industry. Useful tools that can be employed are the PESTLE analysis and Porter's Five Forces framework.

PESTLE analysis is a framework used to analyze the external macro-environmental factors that may affect a business or organization. PESTLE stands for Political, Economic, Sociocultural, Technological, Legal, and Environmental factors (Wysocki, 2019). By analyzing these factors, a business can identify potential opportunities and threats in the market and adjust their strategy accordingly. Below, Wysocki's framework was adapted for the pharmaceutical industry.

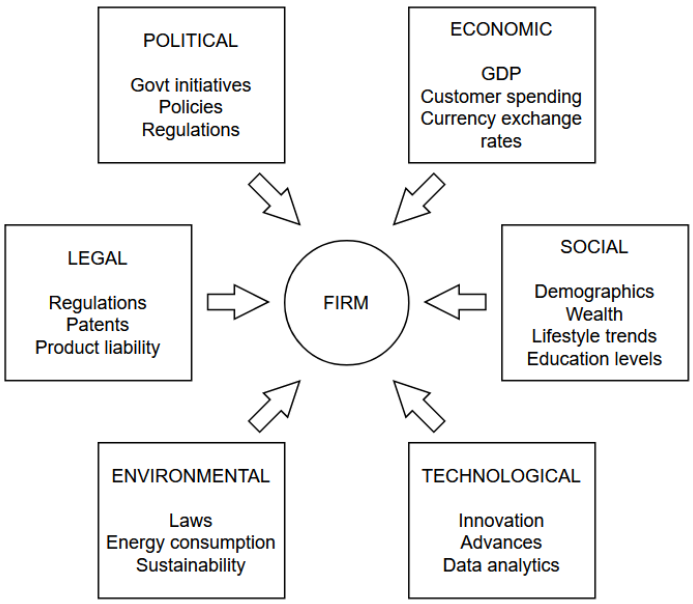

Figure 4: PESTLE framework adapted for the pharmaceutical industry by the Author

Political Factors: Among the political factors are government initiatives, which may include government policies, regulations, and laws related to healthcare, intellectual property rights, but also pricing, and drug approvals can significantly impact the pharmaceutical industry. For example, changes in government policies regarding drug pricing can alter the industry's profitability.

Economic Factors: The pharmaceutical industry is highly dependent on the global economic conditions. Economic factors such as GDP, inflation rates, interest rates, and currency exchange rates can impact the industry's revenue and profitability. Customer spending also has a significant impact on the pharmaceutical industry and their field of interest.

Sociocultural Factors: The demographic shifts, population growth, wealth, lifestyle changes, education levels and consumer preferences are significant factors in the pharmaceutical industry. These factors can influence the demand for drugs and medical treatments.

Technological Factors: The pharmaceutical industry relies heavily on research and development to create new drugs and treatments. The advancements and innovations in technology, such as artificial intelligence and big data analytics, can significantly impact the industry's research and development capabilities.

Environmental Factors: Environmental factors such as climate change and natural disasters can impact the pharmaceutical industry's supply chain, particularly the sourcing of raw materials. Laws regarding the environment and current environmental trends (concerning sustainability and energy efficiency) can also have an influence on the pharmaceutical industry.

Legal Factors: The pharmaceutical industry is heavily regulated by various laws and regulations related to drug development, approval, and marketing. Patents and product liability are important topics within this area, the industry's operations and profitability can be affected by changes in laws and regulations.

On the other hand, Porter's Five Forces is a framework used to analyze the competitive forces within an industry or market. The five forces include the threat of new entrants, the bargaining power of suppliers, the bargaining power of buyers, the threat of substitute products or services, and the intensity of competitive rivalry (Wysocki, 2019). This framework helps businesses understand the competitive landscape and make strategic decisions on how to position themselves within the market of their industry. With regards to the pharmaceutical industry, the five forces are:

- Threat of new entrants: The pharmaceutical industry has high barriers to entry, including high research and development costs, regulatory requirements, and intellectual property protection. As a result, the threat of new entrants is relatively low.
- Bargaining power of suppliers: Pharmaceutical companies rely heavily on their suppliers for raw materials, such as active pharmaceutical ingredients (APIs) and excipients. However, the bargaining power of suppliers is relatively low due to the large number of suppliers available and the ability of pharmaceutical companies to switch suppliers if needed.
- Bargaining power of buyers: The bargaining power of buyers in the pharmaceutical industry is relatively high due to the availability of generic drugs and the increasing role of payers (such as insurance companies and government programs) in drug pricing decisions.
- Threat of substitute products or services: The pharmaceutical industry faces a moderate threat of substitute products or services, particularly from alternative therapies such as natural remedies or medical devices. However, the high regulatory requirements for drug approval act as a significant barrier to entry for substitute products.
- Intensity of competitive rivalry: The intensity of competitive rivalry within the pharmaceutical industry is high, with several large players competing for market share. These companies invest heavily in research and development and marketing to maintain their positions. Patent protection for their products is also an important

factor that affects the intensity of rivalry. When patents expire, there is increased competition from generic drug manufacturers.

Overall, the pharmaceutical industry is highly impacted by various external macro-environmental factors such as political, economic, sociocultural, technological, legal, and environmental factors. The pharmaceutical industry relies on research and development to create new drugs and treatments and must remain aware of it competitors. Porter's Five Forces framework can help understand the competitive landscape of the pharmaceutical industry, with high barriers to entry for new players, low bargaining power of suppliers, high bargaining power of buyers, moderate threat of substitute products or services, and high intensity of competitive rivalry. This industry is highly competitive, with several factors influencing the competitive landscape, including regulatory requirements, intellectual property protection, and the availability of substitute products or services.

3 Patent documents

Patent documents play a crucial role in protecting and promoting innovation in various fields, including technology, medicine, and engineering. They provide inventors with legal rights to prevent others from using, manufacturing, or selling their inventions for a certain period, in exchange for public disclosure of the invention's details. Patent documents also serve as a valuable source of information for researchers, entrepreneurs, and policymakers, providing insights into the latest technological advancements and market trends. This section explores the basics of patent documents, including their structure, language, and legal requirements while discussing the importance of conducting patent searches and the various tools and resources available for patent research.

A European patent is a legal document that grants the owner (or owners) of the patent the exclusive right to make, use, and sell the invention covered by the patent in the countries where it is granted. This means that no one else can make, use, or sell the invention without the permission of the patent owner, unless they are authorized to do so by law. According to the European Patent Convention[2] (EPC) a patent is "a legal title granting its holder the right to prevent third parties from commercially exploiting an invention, in a certain geographical area and for a certain period of time" (EPO, 2020:4), the geographical area regarding the European Patent Office (EPO) consists of 38 contracting states[3] and the duration of patent protection (for both European and US patent protection) is 20 years from the filing date of the patent application. The duration of a patent can be extended in certain circumstances.

There are many differences between European and American patents, the main differences between them are in terms of jurisdiction, the application process, with regards to the examination process. A European patent is granted by the EPO and is valid in all the countries that have ratified the EPC, while an American patent is granted by the United States Patent and Trademark Office (USPTO) and is valid only in the United States. The application process for a European patent is centralized, meaning that a single application can be filed with the EPO[4], and if granted, the patent will be valid in all the countries that

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[2] The European Patent Convention (EPC) is an international treaty that establishes a single patent application and examination procedure for the grant of European patents. The European Patent Office (EPO) is the organization responsible for carrying out this procedure and granting European patents. The EPO is established under the EPC and operates in accordance with the rules and procedures set out in the Convention.

[3] The European Patent Convention (EPC) has 38 contracting states, which are: Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom (excluding some overseas territories).

[4] "When applying for a patent you can choose between following the national procedure in each state for which you want protection or taking the European route, which in a single procedure confers protection in all the contracting states that you want. In this case you can further choose to follow

have ratified the EPC. Similarly, the USPTO has a centralized system for processing patent applications, and once a patent is granted, it is valid throughout the entire United States. Another difference between the application processes for European and American patents is that a European patent application must be filed in one of the official languages of the EPC, which include English, French, and German. However, the application can be translated into one of these languages if necessary. In contrast, an American patent application must be filed in English. Furthermore, the examination process and timing can vary between an American and a European patent, but also depending on the technology area, the complexity of the invention, and other factors, so it can be difficult to make a blanket statement about the rigor of one examination process over another or the duration of the entire process.

The functionality of patents can be summarized as follows: to provide the patent owner with legal protection for their invention in the countries where it is granted for a given amount of time from the filing date, to give the patent owner a monopoly over the invention covered by the patent (preventing others from using, making, or selling the invention without their permission), licensing (permitting the patent owner to allow others to use, make, or sell their invention in exchange for a fee or other compensation), ensuring enforcement of the owner's rights and seeking damages or other remedies in the event of infringement, and encouraging innovation by providing inventors with an incentive to invest time, money, and effort into developing new and useful inventions, knowing that they will be able to protect their creations and reap the rewards of their innovation (Hunt, 2007).

Overall, a patent provides the patent owner with a valuable asset that can be used to protect their intellectual property rights, generate revenue through licensing or commercialization, and encourage further innovation in their field. In addition, obtaining a patent can also provide the patent owner with a competitive advantage in the marketplace by preventing others from using, making, or selling the same invention without permission. This can be particularly important in industries where research and development are costly and time-consuming, as it can help ensure that the inventor is able to recoup their investment and maintain a foothold in the market. Furthermore, patents can also be used as collateral for financing and can increase the value of a company in the eyes of investors and potential buyers. However, the process of obtaining a patent can be complex and costly, and it is important for inventors to carefully consider the potential benefits and drawbacks before pursuing patent protection.

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the Euro-PCT route, under which the first phase of the grant procedure is subject to the Patent Cooperation Treaty (PCT), while the regional phase before the EPO is governed by the EPC" (EPO, 2020:6).

3.1 Patent components

In addition to realizing the benefits of obtaining a patent, it is important for inventors and companies to have a clear understanding of the components that make up a patent. This includes the patent classification system and the various required sections that make up a patent. By understanding these components, patent owners can ensure that their patents are properly classified, and that all necessary information is included.

3.1.1 Patent classification system

European patents are classified according to the International Patent Classification (IPC) system, which is a standardized system used to classify patents based on the technical subject matter they cover. The IPC system is maintained by the World Intellectual Property Organization (WIPO) and is used by patent offices around the world (Hunt, 2007). The IPC system uses a hierarchical structure to classify patents into different categories based on their technical content.

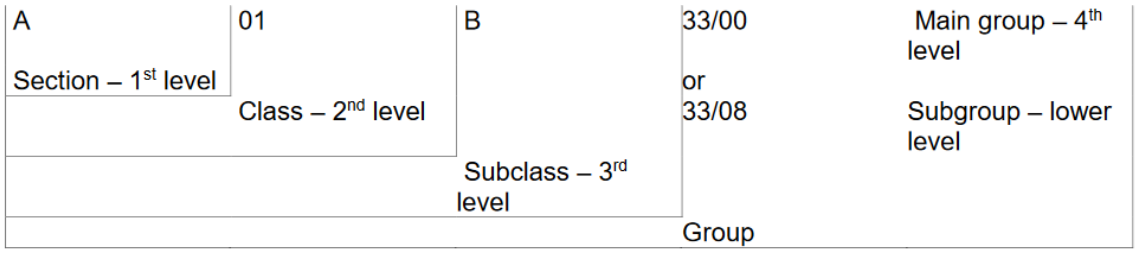

Figure 5 Example of a complete classification symbol (Guide to IPC, 2023:6)

According to the *Guide to the International Patent Classification* from the year 2023, at the highest level, the classification is divided into eight sections, which cover the following areas:

A - Human Necessities

B - Performing Operations; Transporting

C - Chemistry; Metallurgy

D - Textiles; Paper

E - Fixed Constructions

F - Mechanical Engineering; Lighting; Heating; Weapons; Blasting

G - Physics

H - Electricity

Each section is then further divided into classes, subclasses, and groups, with each level providing more specific detail about the technical content of the patent. A complete classification symbol consists of a hierarchical sequence combining the symbols representing the section, class, subclass and main group or subgroup.

The IPC system allows patent examiners, attorneys, and inventors to search for patents based on their technical content, regardless of the language or terminology used in the patent documents. This makes it easier to identify prior art and to determine the scope of protection provided by a particular patent.

Pharmaceutical drugs and chemicals could generally fall into section C - Chemistry; Metallurgy of the International Patent Classification (IPC) system as this section covers a wide range of technical subject matter related to chemistry, including pharmaceuticals, cosmetics, and other chemical compositions. However, pharmaceutical drugs are typically classified in subclass A61K[5], which covers preparations for medical, dental, or toilet purposes. This subclass is further divided into groups based on the specific type of preparation, such as for internal use, for topical use, or for use in specific medical conditions.

Other subclasses that may be relevant to pharmaceutical drugs and chemicals include:

A61P - Therapeutic activity of chemical compounds or medicinal preparations: This subclass covers patents related to the use of chemical compounds or medicinal preparations for the treatment of specific medical conditions.

C07D - Heterocyclic compounds: This subclass covers patents related to the synthesis and use of heterocyclic compounds, which are a class of chemical compounds that contain a ring structure with atoms other than carbon (e.g., nitrogen, oxygen, sulfur).

C07K - Peptides: This subclass covers patents related to the synthesis and use of peptides, which are short chains of amino acids that can have a variety of biological functions.

G01N: Investigating or analyzing materials by determining their chemical or physical properties, e.g., testing composition or purity of pharmaceuticals.

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[5] Pharmaceuticals are classified under section A of the IPC because the primary focus of pharmaceuticals is on their use for medical, dental, or toilet purposes rather than their chemical composition. Section A of the IPC is dedicated to "Human Necessities," which includes inventions related to health, hygiene, and personal care. On the other hand, section C of the IPC is for "Chemistry; Metallurgy," which covers inventions related to chemistry and metallurgy, regardless of their intended use. While pharmaceuticals are a type of chemical composition, their primary use and intended purpose fall under the "Human Necessities" category. Therefore, it makes sense to classify them under section A and subclass A61K, which is dedicated to preparations for medical, dental, or toilet purposes.

While pharmaceutical drugs and chemicals are typically classified in the subclass A61K of the IPC, they may also be classified in other sections or subclasses depending on their specific technical content.

3.1.2 Patent sections

European patents consist of several sections that provide important information about the invention and its protection. A granted patent will then have the following sections:

Front Page: This includes the title of the invention, the patent number (a unique identifier assigned to a granted patent), document type, the names of the inventors, the applicant's name and address, the filing date, the date of Patent Publication, the IPC number, the INID number (the International Numbering for Identification of Data number, which is a standardized numbering system that is used to identify specific information in a patent document) and the patent application number.

Description: This section provides a detailed description of the invention, including its technical features, operation, and potential applications.

Claims: This section defines the scope of protection sought by the patent owner. The claims specify the features of the invention that are considered to be novel and inventive, and set out the boundaries of the patent protection.

Drawings: This section includes any drawings or diagrams that are necessary to understand the invention.

Abstract: This section provides a brief summary of the invention, including its technical field, the problem it solves, and its key features.

Prior Art References: This section lists any prior art references that are relevant to the invention, including patents, scientific articles, and other technical documents.

Patent Grant: This section provides the official grant of the patent by the European Patent Office (EPO) and includes the patent number and date of grant.

The format and content of a European patent may vary slightly depending on the specific requirements of the EPO and the country or region in which the patent is filed. However, the sections listed above are typically included in all European patents.

3.2 Patent application process

According to the European Patent Guide that is available on the official EPO website, the process of obtaining a European patent consists of several steps:

Filing the application with the EPO
Formalities examination of the application
European search report and written opinion on patentability

Publication of the application
Substantive examination of the application
Grant of the European patent if the application is found to be patentable.

Filing: The first step is to file a European patent application with the EPO. This can be done either directly with the EPO or through a national patent office. To file a European patent application with the EPO, the applicant must use the EPO Form 1001 (Request for Grant). The form includes information about the applicant, the inventor, and the invention itself.[6] The applicant must also pay a filing fee and provide a description of the invention, along with any necessary drawings or other supporting materials. After submitting the form, the applicant will receive an acknowledgment of receipt (containing the filing date and number).

Formalities examination: The formalities examination of a European patent application involves an initial review by the EPO to ensure that the application meets certain formal requirements. During this stage, the application undergoes an examination on filing to receive a date of filing. Once the application has received a date of filing, the Receiving Section of the EPO will check the following aspects (EPO, 2020:53):

- the translation, if required
- the content of the Request for Grant form
- the presence of claims
- the abstract
- representation
- formal requirements
- priority claimed
- designation of the inventor
- filing of any drawings

This step ensures that the application has been filed with the required documents and in the required format, in the official languages of the EPC, that the fees have been paid and the applicant has been identified. If any of these requirements are not met, the EPO will issue a communication requesting that the applicant provide the missing information or take corrective action. Once the formalities examination is completed, the application is considered to be "pending" and will move on to the next stage of the European patent grant procedure.

Search: The EPO carries out a search to determine whether the invention meets the criteria for patentability. “While the formalities examination is in progress, the European search is performed.” (EPO, 2020:54) The EPO prepares a search report based on the claims, as well as the description and drawings provided in the patent application. The search report, along with an opinion and copies of the relevant documents, are then sent to the applicant.

[6] “A European patent application consists of a request for the grant of a European patent, a description of the invention, one or more claims, any drawings referred to in the description or claims, and an abstract.” (EPO, 2020)

According to the EPO Guide, at this stage the applicant can either withdraw the application or decide to pursue the procedure.

Publication: The application is published by the EPO "18 months after the date of filing or the earliest priority date". (EPO, 2020:55) Upon publication of the search report in the European Patent Bulletin, the EPO will notify the applicant of the publication date and draw their attention to the deadline for requesting examination. This deadline starts on the date of publication of the search report. Additionally, the publication date also serves as the starting point for the six-month period within which the applicant must pay the examination fee, as well as any designation and extension/validation fees that may be applicable.

Examination: The EPO examines the application to determine whether the invention meets the criteria for patentability. This includes an assessment of novelty, inventive step, and industrial applicability. The deadline for filing the request for examination is six months from the date of publication of the European search report in the European Patent Bulletin. The request must be submitted in writing and is included in the Request for Grant form, but it will only be considered filed after payment of the examination fee. Once the request is filed, it cannot be withdrawn. During this same six-month period, the applicant will also receive an invitation to provide comments on the extended European search report, address any deficiencies noted in the accompanying opinion, and make appropriate amendments to the description, claims, and drawings. (EPO, 2020) After the request for examination is filed, the EPO will conduct an examination to determine if the application and invention meet the patentability requirements based on the search report and the applicant's response to it. It is recommended for the applicant to address all examiner objections in a single response, but it is possible to request oral proceedings if necessary. If the examining division finds that the application meets the requirements of the EPC, they will grant a European patent. However, if the application does not meet the requirements, the division will reject the application.

Opposition: Once the patent is granted, it can be opposed by third parties within a certain time period (up to nine months after publication)[7]. This allows for challenges to the validity of the patent. The grounds of opposition can be that the patent's subject-matter is not patentable within the terms of EPC[8], that the patent is insufficiently clear and complete for a person skilled in the art to carry out the invention, or the patent covers subject matter that goes beyond what was originally disclosed in the application. (EPO, 2020) After the notice of opposition is received, the opposition division examines its admissibility and then proceeds with a substantive examination. If the opposition division concludes that the grounds for opposition are valid, it will revoke the patent. On the other hand, if the opposition division finds that the grounds for opposition are not sufficient to challenge the patent as granted, it will reject the opposition. Another possible outcome is that the

[7] Opposition of a patent also requires payment: "Notice of opposition is not considered to have been filed until the opposition fee has been paid." (EPO,2020: 60) The Notice of opposition must be filed within the opposition period and must contain at least one ground for opposition, while indicating the facts, evidence and arguments presented in support of the grounds (EPO, 2020).
[8] Articles 52-57

opposition division determines that the patent can be upheld in a modified version. Any party to the proceedings adversely affected by a decision may file an appeal, which will be reviewed by the boards of appeal. In certain cases, it is possible to file a petition for review by the Enlarged Board of Appeal.

Validation: Once the patent is granted, it must be validated in each of the designated countries where the applicant wishes to have protection. This involves paying fees and complying with local regulations. Validation is a separate process that takes place after the grant of a European patent, which allows the patent to take effect in individual countries designated by the patent holder. The process of validation is governed by national laws and regulations of each individual country, and it is not part of the European patent grant procedure conducted by the EPO.

3.2.1 Modeling of the Application Process

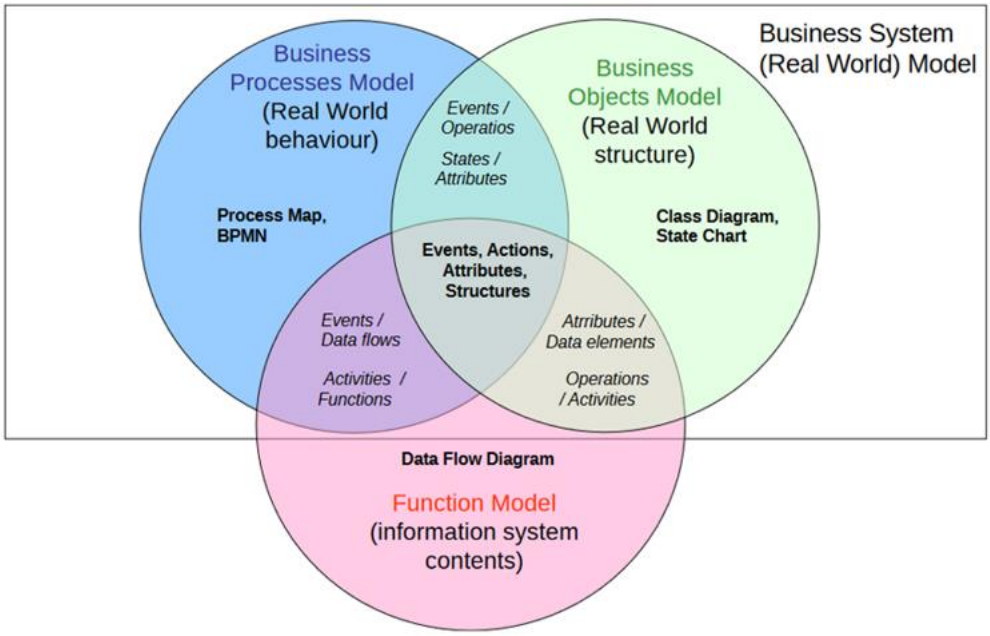

Figure 6 MMABP models (Řepa, 2021:12)

The Methodology for Modelling and Analysis of Business Processes (MMABP) is a framework designed to model and analyze business processes. According to Řepa (2012), modeling involves providing a formal representation of a phenomenon or system that serves as an articulation of reality, using appropriate visualization tools to simplify the depiction of the system and highlight only the features that are essential to achieve the modeling goal.

In the MMABP methodology, the Real World ontology is modeled according to specific rules. Real-world behavior is represented through models that express the relevant behavior of business actors as a system of business processes. The Business Processes model encompasses events and actions and includes Process map diagrams, the Eriksson/Penker diagram, TOGAF event diagram, and the BPMN Process diagram. The Business Objects

model focuses on attributes and methods and includes the Class diagram and the State Chart diagram. By integrating these two models, MMABP provides a comprehensive framework for modeling and analyzing business processes, with the Business Processes model emphasizing temporal aspects and the Business Objects model focusing on structural and functional aspects. This integrated approach enables the development of complex models that can capture the full range of business process behavior, facilitating the identification of areas for improvement and optimization.

A process map diagram is a visual representation of a process and its different stages. It is used to model and analyze the workflow and steps involved in completing a task or achieving a goal. Process map diagrams are useful for identifying areas of inefficiency or potential improvement in a process, as well as the inputs, outputs, and tasks that are involved in each stage.

The process map diagram below shows the key process Patent application process, that has four subprocesses: formalities examination of the application, patentability search by EPO, publication subprocess of the application and substantive examination of the application. This diagram is from the point of view of the patent applicant, whereas literature that discusses patent processes may present the processes from different perspectives, such as from the point of view of the patent office or patent examiner.

The formalities examination subprocess involves verifying that the application meets the formal requirements for submission, such as correct filing fees, required forms, and complete documentation. The patentability search by EPO involves searching prior art to determine if the invention is novel and non-obvious, and if there are any similar patents or patent applications that may impact the application. The publication subprocess of the application involves publishing the application in the appropriate patent journal, which triggers a period for third parties to oppose or comment on the application. The substantive examination of the application involves reviewing the application in detail to determine if it meets the legal requirements for patentability, such as novelty, non-obviousness, and industrial applicability.

Overall, this diagram provides an overview of the key subprocesses involved in the patent application process, from the perspective of the patent applicant. It highlights the importance of meeting formal requirements, conducting a patentability search, publishing the application, and undergoing substantive examination to obtain a patent. Interestingly,

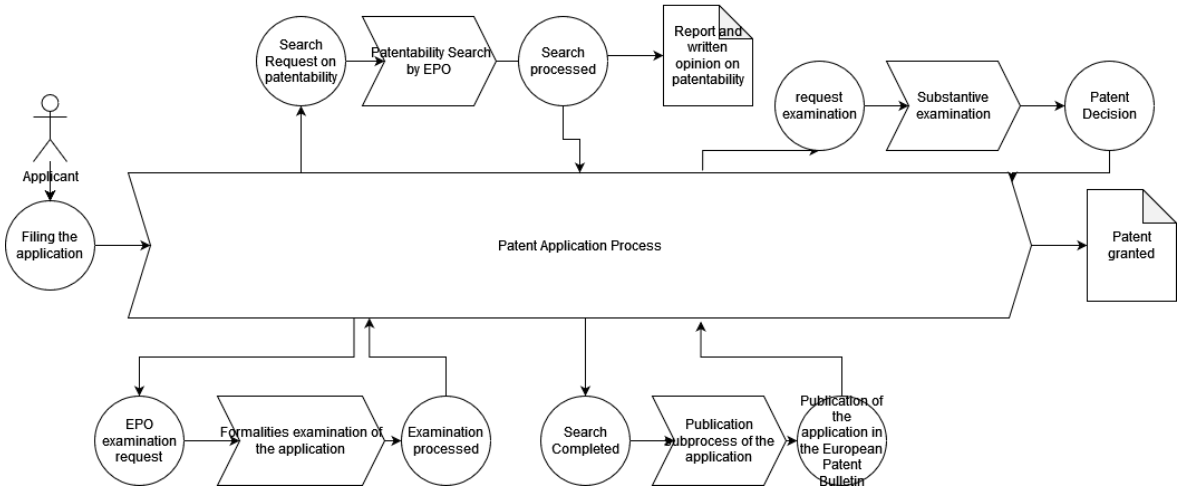

Figure 7 Patent Application Process, by the Author

While the diagram provides a clear overview of the patent application process from the perspective of the applicant, literature on patent searching, such as Hunt's *Patent Searching: Tools and Techniques*, often addresses the process from the perspective of the examiner and approaches the process differently. Hunt's work highlights the importance of scoping the search, conducting the search, analyzing the results, and making decisions based on the findings. The scoping process involves identifying subject features, generating keywords, selecting classification areas, and reviewing closely related patents. The search process is focused on quickly finding relevant documents and accurately assessing their relevancy. Evaluating patent documents is a key aspect of the search process, with different types of searches requiring different approaches, such as classification searching, full-text searching, citation searching, and searching foreign patent documents. Additionally, non-patent literature is also important to consider in the search process. Overall, while the patent application process is a complex one, with different perspectives and approaches depending on whether from an applicant's or an examiner's prospective, understanding the key subprocesses and best practices can help ensure a successful outcome.

According to the USPTO official website, the Patent Application process has the following steps:

> Determine the type of Intellectual Property protection that the applicant needs (the choice being between patents, trademarks, servicemarks, and copyrights).
> Determine if the invention is patentable, for which the USPTO offers several resources.
> Determine what kind of patent the applicant needs (Utility, Design or Plant).
> Preparation for application: decision concerning the types of patent applications and proceedings (Provisional Application for Patent, Nonprovisional (Utility) Patent Application, Design Patent Application, Plant Patent Application, international application under the PCT), consideration of the application strategy and the use of professional legal services.
> Submission of the initial application.
> Examination – completeness check and content examination.

Patent approval.
Patent maintenance.

As evident from the above, filing for a patent at the EPO and the USPTO follow similar (with determining patentability, preparing and submitting the application, there being an examination of the application and there being a granting of the patent, if the application meets the requirements) but not identical processes. The process also differs with regards to the appeal's system that is different in the United States and Europe. Further information concerning the appeals may be found in the Appendix section (Appendix A) of this MT.

4 TI Implementation proposal

TI is a necessary practice that companies and organizations undertake to maintain their competitive edge within their area of business. TI involves the collection, analysis, and interpretation of information related to technology, competitors, customers, and other relevant factors. Two critical components of TI are patent and non-patent document research. In patent research, companies analyze and monitor patent filings and publications to identify emerging technologies, competitive threats, and potential licensing opportunities. Non-patent document research involves analyzing various other sources of information, such as scientific literature, market reports, and regulatory filings, to gain insights into emerging trends, market dynamics, and potential competitors. TI is typically conducted in phases, each of which involves specific activities and objectives. This chapter provides an overview of the different phases of TI implementation, as well as the key components of patent and non-patent document research. The phases of the TI life cycle are Planning or the formulation of needs, Data collection, Analysis with reporting and Decision-making/action.

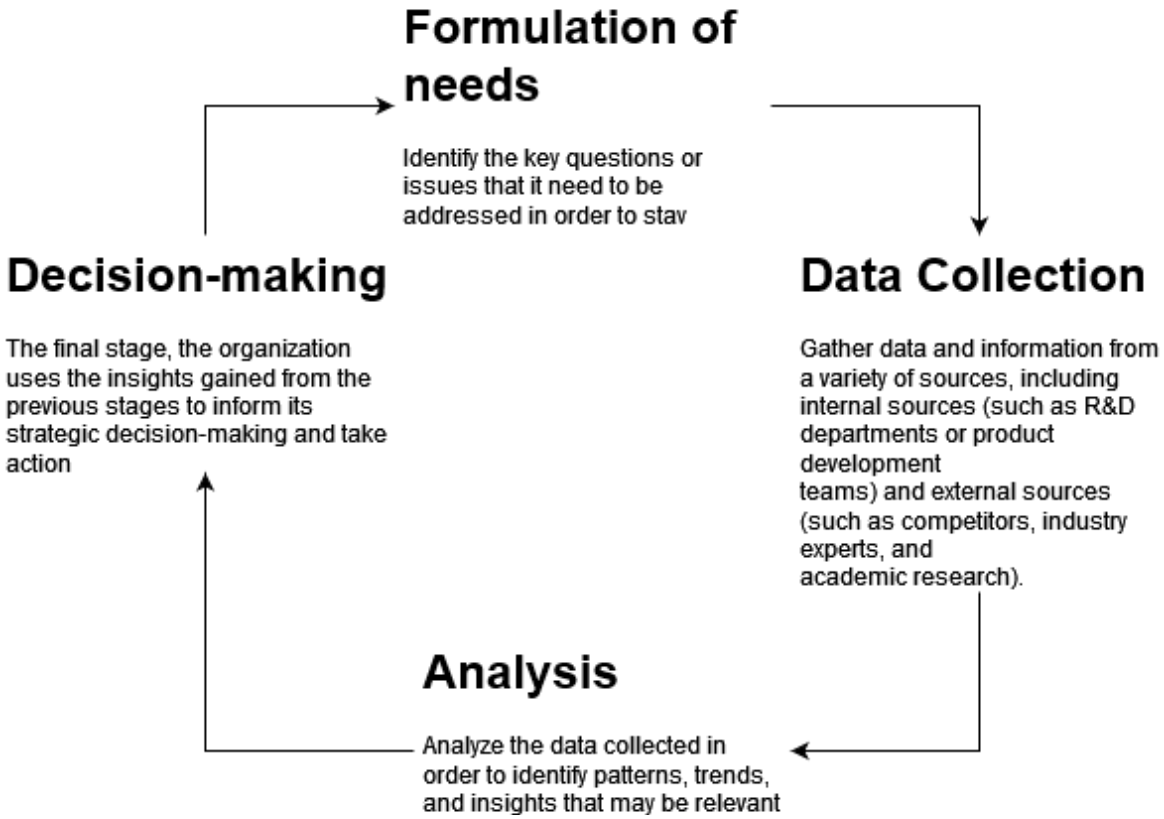

Figure 8 TI Life cycle, by the Author

Planning: In this phase, the objectives of the study are defined, the research questions are refined, and the scope of the project is defined. The research team will also identify the target market, key competitors, and other relevant factors that will guide the research process. KIT (Key Intelligence Topics) and KIQ (Key Intelligence Questions) are

typically introduced during the planning phase of a TI study. During this phase, the research team identifies the key objectives of the study and defines the research questions.

KITs and KIQs are important tools that help the research team focus their efforts on the most relevant and important areas of inquiry. KITs refer to the main topics or areas of interest that the CTI study will cover, while KIQs are the specific questions that the research team will seek to answer within each KIT (Herring, 1999). By defining KITs and KIQs early on in the planning phase, the research team can ensure that their efforts are focused on the most important and relevant areas of inquiry, and that the resulting CTI study will provide actionable insights that can inform decision-making.

Data Collection: In this phase, the research team collects relevant data from a variety of sources, including patent databases, scientific literature, regulatory filings, and other sources of information. The data is then organized and stored in a database or other system that can be used to analyze and interpret the results. An important part of this step is brainstorming potential keywords to help find the needed information. These keywords should be relevant to the scope and objectives of the search and also specific enough to help narrow the results to obtain relevant information. A part of this process is refining and expanding the keywords to ensure comprehensibility and inclusion of relevant information. This often involves adding synonyms, acronyms, or variations of the keywords. Once identified and refined, the keywords should be tested for their effectiveness in finding the relevant information, by conducting test searches using the keywords and evaluating the search results. If repeating the TI cycle, it is also important to monitor and update keywords over time to ensure that they remain relevant and effective.

Data Analysis: In this phase, the research team analyzes the collected data to identify trends, patterns, and other key insights that can help inform decision-making. This may involve using statistical analysis, machine learning algorithms, or other analytical and visualization tools to identify key insights.

The Decision-making stage includes reporting and implementation. Reporting: In this part of the final phase, the research team prepares a report that summarizes the key findings of the study. The report may include detailed analysis of patent and non-patent documents, as well as recommendations for next steps, such as further research, product development, or changes to the company's strategic plan. Implementation: In this part of the phase, the company may take action based on the findings of the CTI study. This may involve developing new products or technologies, filing new patents, or adjusting the company's strategy based on the competitive landscape.

5 Case study

This work examines three model groups of pharmaceuticals, each of which will undergo the TI cycle. The first group is synthetic hormonal treatment for hypothyroidism, a condition that occurs when the thyroid gland fails to produce enough thyroid hormones. The second group consists of non-steroidal anti-inflammatory drugs (NSAIDs), which are commonly used to alleviate pain and reduce inflammation. The third group comprises of anti-cancer drugs, which are used to treat cancer through different mechanisms, including chemotherapy, targeted therapy, and immunotherapy. Through the TI cycle, this study aims to gather information on the current and emerging treatments for each model group and identify trends, patterns, and gaps in the current treatment landscape. This information can inform the development of new treatments, improve patient outcomes, advise regulatory decisions, and pricing strategies for these medications.

To implement the TI cycle for each of the model groups of drugs, the following steps were taken:

Planning and defining the scope of the TI: in this phase the objectives of the study were defined with regards to the three model groups of pharmaceuticals, and the scope of the project was defined. The first step was to define the scope of TI, which was to gather information on the current and emerging treatments for each model group. This included information on the types of medications available, their mechanisms of action, their efficacy, and side effects. Then, the Key Intelligence Topics (KITs) and Key Intelligence Questions (KIQs) were articulated.

The selected KITs for the three model groups are a competitive analysis - identifying competitors and their patent protection in different territories for each model group and identifying the current development trends in the three groups.

The KIQs are the same for each model group:

1. Who are the main competitors in the field, and in which territories are they seeking patent protection?
2. What are the current development trends within the three groups?

Identifying information sources: Next, the sources of information that will be used to gather intelligence were identified. This included scientific publications obtained through WoS, Scopus, PubMed and PubChem, and patents.

Collecting data: The third step is to collect the data from the identified sources. This involved conducting searches using keywords related to hypothyroidism, NSAIDs and anti-cancer drugs and their treatment and reviewing published research papers. Each selection will be explained in detail in the following subchapters dedicated to each model group.

Analyzing the data: The collected data was then analyzed to identify trends, patterns, and gaps in the current treatment landscape. This step involved using data visualization tools, such as graphs and charts, to better understand the data.

Reporting and disseminating findings: Finally, the findings of the TI should be reported and disseminated to relevant stakeholders, such as researchers, clinicians, and pharmaceutical companies. This could involve creating a report or presentation summarizing the findings and hosting a workshop or seminar to present the findings and gather feedback. In this particular case, this step will be taken within this work and not communicated to any third party.

By implementing the TI cycle, we can gain valuable insights into the current and emerging treatments for each group, which can inform the development of new treatments and improve patient outcomes. Additionally, this information can be used to advise regulatory decisions and pricing strategies for these medications.

5.1 Model group 1 - Hypothyroidism

This thesis examines three model groups of pharmaceuticals. The first group consists of the hormonal treatment of hypothyroidism. Hypothyroidism is a condition that occurs when the thyroid gland does not produce a sufficient amount of thyroid hormones. The thyroid gland is a small butterfly-shaped gland located in the neck that produces two primary hormones: thyroxine (T4) and triiodothyronine (T3), that regulate metabolism and other bodily functions.

There are various medications to treat thyroid gland disorders, which can be categorized into two groups: those used for underactive (hypothyroidism) and overactive (hyperthyroidism) thyroid glands. Synthetic thyroid hormones, such as levothyroxine, are commonly prescribed to replace missing thyroid hormones and restore normal thyroid function in hypothyroidism. Antithyroid drugs like propylthiouracil and methimazole are used to treat hyperthyroidism by blocking thyroid hormone production and reducing symptoms. Other treatments for thyroid disorders include surgery and various therapies used alone or in combination with medication. However, this study solely focuses on treatments for the reduced function of the thyroid gland, hypothyroidism. The focus on hypothyroidism treatments in this study is due to its prevalence and impact on individuals' quality of life.

Hypothyroidism is a common condition affecting millions of people worldwide, and its symptoms can range from mild to severe, impacting various aspects of daily life. The history of hypothyroidism treatment dates back to the late 19th century when clinicians started using thyroid gland extracts to treat hypothyroidism. In the 1920s, the active ingredient in the thyroid gland was identified as iodine, and iodine supplements were used to treat iodine deficiency-induced hypothyroidism. In the 1950s, the first synthetic thyroid hormone, levothyroxine, was introduced, and it quickly became the standard treatment for hypothyroidism (Chiovato, 2019). Levothyroxine is a synthetic version of the thyroid hormone thyroxine (T4) and is designed to replace the missing thyroid hormones in the body. Since its introduction, levothyroxine has undergone several improvements, and today

it is the most commonly prescribed medication for hypothyroidism (Duntas, 2019). Other medications used to treat hypothyroidism include liothyronine, a synthetic version of the thyroid hormone triiodothyronine (T3), and desiccated thyroid extract, which contains a combination of T3 and T4. However, levothyroxine is generally considered the preferred treatment due to its consistency, safety, and effectiveness.

After defining the scope of this model group, and confirming the KITs and KIQs, it was time to move on to the Data Collection phase, which included the formulation of relevant keywords. The initial stage was to consider possible keywords and refine them as needed to obtain relevant information. These possible keywords were then either confirmed or removed from the list and can be found in the Appendix of this work.

Using the refined keywords, a search was conducted on the PatentScope database using the following query:

Precision

(((EN_TI:Hypothyroidism) OR (EN_AB:Hypothyroidism) OR (EN_CL:Hypothyroidism) OR (EN_TI:levothyroxine) OR (EN_AB:levothyroxine) OR (EN_CL:levothyroxine) OR (EN_TI:"C15H11I4NO4") OR (EN_AB:"C15H11I4NO4") OR (EN_CL:"C15H11I4NO4") OR (EN_TI:"synthetic thyroid hormones") OR (EN_AB:"synthetic thyroid hormones") OR (EN_CL:"synthetic thyroid hormones") OR (EN_TI:"Hashimoto's thyroiditis") OR (EN_AB:"Hashimoto's thyroiditis") OR (EN_CL:"Hashimoto's thyroiditis") OR (EN_TI:"congenital hypothyroidism") OR (EN_AB:"congenital hypothyroidism") OR (EN_CL:"congenital hypothyroidism"))) AND (IC:"A61K 31/55")

This is a search query that includes keywords related to hypothyroidism and its treatment. The search query uses Boolean operators (OR and AND) to combine different keywords and phrases to find relevant results. Specifically, the query includes the following search terms:

Hypothyroidism
Levothyroxine
C15H11I4NO4 (the chemical formula for levothyroxine)
Synthetic thyroid hormones
Hashimoto's thyroiditis
Congenital hypothyroidism

The query also includes a filter that restricts the search to documents with an International Patent Classification (IPC) code of "A61K 31/55", which is a classification for therapeutic compounds used to treat thyroid disorders. Overall, the query is designed to find documents related to the treatment of hypothyroidism and related conditions using levothyroxine or synthetic thyroid hormones.

This search was a Precision search measuring how accurate the model is in identifying relevant results. It is defined as the ratio of true positives (correctly identified relevant results) to the sum of true positives and false positives (incorrectly identified relevant results). In other words, precision measures the proportion of retrieved results that are relevant.

Precision = (number of relevant documents retrieved) / (Total number of documents retrieved)

The patent code A61K 31/55 refers to a subgroup of the broader A61K31 class which relates to therapeutic preparations containing organic compounds. More specifically, A61K31/55 relates to the use of steroids as active ingredients in these preparations.[9] The code covers "Medicinal preparations containing organic active ingredients" with a particular focus on compounds used for "specific therapeutic activity of chemical compounds or medicinal preparations" and within this subclass, the section 55 relates to compounds that have therapeutic activity for thyroid disorders (IPCPUB WIPO, 2023:A61K31/55).

On the 23rd of April 2023, this search had 192 results. When repeating the same search on the 27th, the number of results was 193.

Recall

(((EN_TI:Hypothyroidism) OR (EN_AB:Hypothyroidism) OR (EN_CL:Hypothyroidism) OR (EN_TI:levothyroxine) OR (EN_AB:levothyroxine) OR (EN_CL:levothyroxine) OR (EN_TI:"C15H11I4NO4") OR (EN_AB:"C15H11I4NO4") OR (EN_CL:"C15H11I4NO4") OR (EN_TI:"synthetic thyroid hormones") OR (EN_AB:"synthetic thyroid hormones") OR (EN_CL:"synthetic thyroid hormones") OR (EN_TI:"Hashimoto's thyroiditis") OR (EN_AB:"Hashimoto's thyroiditis") OR (EN_CL:"Hashimoto's thyroiditis") OR (EN_TI:"congenital hypothyroidism") OR (EN_AB:"congenital hypothyroidism") OR (EN_CL:"congenital hypothyroidism"))) AND (IC:"A61K*")

Recall measures how well the model retrieves all relevant results. It is defined as the ratio of true positives to the sum of true positives and false negatives (relevant results that were not retrieved). In other words, recall measures the proportion of relevant results that were retrieved out of all the possible relevant results.

Recall = (number of relevant documents retrieved) / (total number of relevant documents in the collection)

On the 23rd of April 2023, this search had 6528 results. The same search yielded 6378 results on the 27th. For the purpose of this case study, the newer results were used.[10]

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[9] Levothyroxine could be included in this category if it meets the criteria of "compounds containing cyclopenta[a]hydrophenanthrene ring systems; Derivatives, e.g. steroids" and "having an oxygen-containing hetero ring" (IPCPUB WIPO, 2023:A61K31/55). Levothyroxine is a synthetic form of the thyroid hormone thyroxine, which has a cyclopenta[a]hydrophenanthrene ring system and an oxygen-containing hetero ring.

[10] There could be several reasons why the PatentScope search yielded different results on different days. Possible explanations can be that new patent application were published in the interim but also patents could be withdrawn or rejected, which would cause results to decrease. Patents could also have been removed from the database. It is also possible but unlikely that there were technical issues with the PatentScope search engine that caused the discrepancy in the search results. This is less likely, but it's worth considering.

In general, precision and recall are inversely proportional to each other. When precision is high, recall tends to be lower, and vice versa. This is because as the model becomes more selective in identifying results (higher precision), it may miss some relevant results (lower recall). On the other hand, as the model becomes more inclusive in identifying results (higher recall), it may include more irrelevant results (lower precision).

Results from both Precision and Recall searches were downloaded into Excel files and then connected to Tableau, a data visualization and business intelligence software that allows users to create interactive and dynamic dashboards, reports, and charts. It enables users to connect to various data sources, including spreadsheets, databases, and cloud services, and visualize the data using drag-and-drop tools. Tableau provides a range of features such as data blending, real-time collaboration, and data storytelling, making it a powerful tool for data analysis and decision-making. It is used by businesses, organizations, and individuals to explore and communicate insights from data. The data was explored, cleaned (removing null values from applicants), organized (grouping together same applicants that had case variation or spelling variation, also grouping together merged companies) and then analyzed with regards to the KIQs.

KIQ1MG1 (The Key Intelligence Question 1 for Model Group 1): Who are the main competitors in the field, and in which territories are they seeking patent protection?

The data from the Precision dataset shows that the top three applicants with the most patents are: Novartis, Pfizer, and Merck.

Novartis is a Swiss multinational pharmaceutical company that produces a wide range of pharmaceutical products, including prescription drugs, over-the-counter medications, vaccines, and diagnostic tests. It was created in 1996 through the merger of Ciba-Geigy and Sandoz (Novartis, 2023).

Pfizer is an American multinational pharmaceutical company that produces prescription drugs, vaccines, and consumer healthcare products. It was founded in 1849 and has since become one of the largest pharmaceutical companies in the world (Pfizer, 2023).

Merck & Co., Inc., commonly known as Merck, is an American multinational pharmaceutical company that produces prescription drugs, vaccines, biologic therapies, and animal health products. It was founded in 1891 and is headquartered in New Jersey, United States (Merck, 2023).

Novartis has 13 patents in the following countries: 1 in the United States, 1 in Canada, 2 in Australia, 3 WO and 6 EP. Pfizer has 10 patents: 1 in Australia, 1 in Bulgaria, 1 in Canada, 1 in Estonia, 2 in EP, 2 in Japan and 2 in Portugal. Merck has 8 patents: 2 EP, 3 in Canada and 3 WO.

WO stands for "World Intellectual Property Organization" which is an international organization that serves as a forum for intellectual property services, policy, and cooperation. WO patents are international patent applications filed under the Patent Cooperation Treaty (PCT), which provides a unified procedure for filing patent applications in over 150 countries. EP stands for "European Patent" and refers to patents granted by the

European Patent Office (EPO) for inventions in European countries. EP patents are valid in the 38 member countries of the European Patent Organization (EPO) and provide protection for inventions in those countries.

The most patent active inventors were the trio William Hewitt, Daniel Lucius Vasella and Randy Lee Webb with 6 patents (5 of which were applied under Novartis). The duo Mui Cheung and Raghuram S. Tangirala have 4 patents (Glaxosmithkline LLC) and Michael David Forrest also has 4 patents (applied under his own name).

In the Recall dataset the results for top applicants were Merck & Co., Inc. (160 patents), Genetech, Inc. (106 patents) and Novartis (103 patents). As for the territory of these patents, the top three for each applicant are Merck & Co., Inc. (WO 39, CA 31, US 27), Genetech, Inc. (WO 39, CA 26, US 21) and Novartis (WO 25, EP 19 and AU16).

Genentech, Inc. is a biotechnology company that specializes in developing and manufacturing therapeutics for treating a range of serious medical conditions. The company was founded in 1976 and is headquartered in South San Francisco, California, United States. Genentech is known for its work in the field of cancer treatment, including the development of the first targeted cancer therapy, Herceptin, which is used to treat breast cancer. The company is a subsidiary of the Swiss pharmaceutical company Roche, and operates as an independent unit within the Roche Group (Genentech, 2023).

When looking solely at the territories, the top three are: WO with 1759 patents, US 1548 patents and CA 1105 patents. In comparison, the Precision dataset's top three countries were US 64, WO 39 and EP 32 patents. From the data provided by PatentScope, it can be concluded that the top three territories where applicants are seeking patent protection for the first model group of pharmaceuticals are WO, US, and CA. Additionally, Novartis is also seeking patent protection in Canada, Australia, and EP. Pfizer is seeking patent protection in Australia, Bulgaria, Estonia, Japan, and Portugal. Merck is additionally seeking patent protection in EP.

KIQ2MG1: What are the current development trends within this model group?

To answer this Key Intelligence Question, a scientific literature search was conducted in Web of Science. The search query below yielded 74760 results.

Search query:

TS=(Hypothyroidism OR levothyroxine OR "C15H11I4NO4" OR "synthetic thyroid hormones" OR thyroxine OR triiodothyronine OR "Hashimoto's thyroiditis" OR "congenital hypothyroidism")

Using the filters available in WoS to refine this search by publication year, document type, language, and other relevant criteria, it is possible to make an estimation of the current trends. Thus, one analysis was conducted upon the dataset of the publications from 2023 (KIQ2MG1a) and another investigated top cited articles regardless of the publication year (KIQ2MG1b).

KIQ2MG1a

WoS

Within the publications from 2023, there were 618 publications this year and the top 15 research areas were:

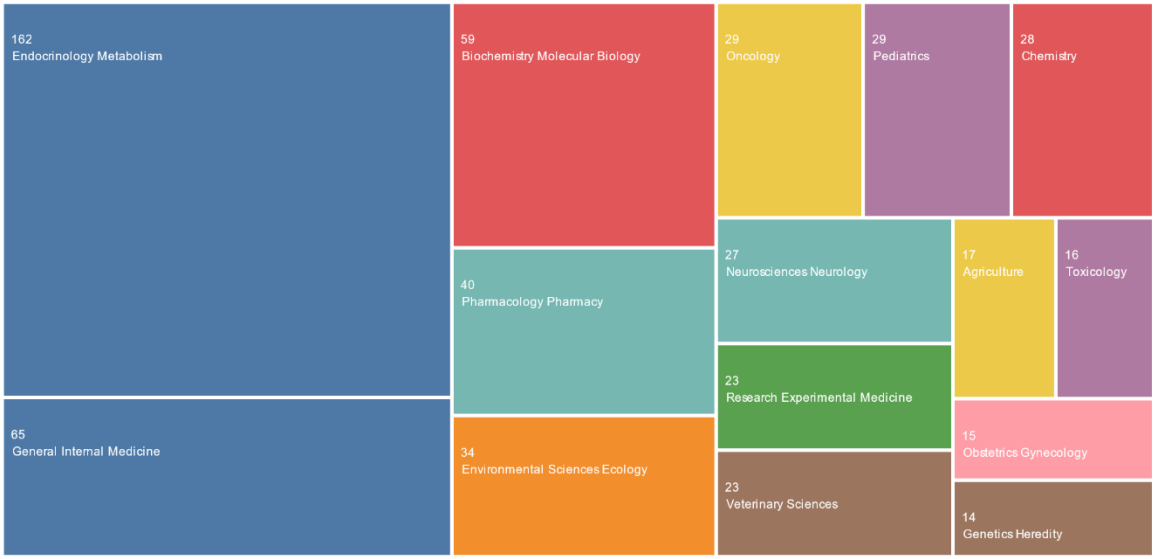

Figure 9 WoS TreeMap Chart of Research areas of the given search (KIQ2MG1a), by the Author

When reviewing the articles from the Pharmacology Pharmacy research area, based on the provided author keywords, it is possible to identify some current trends related to hypothyroidism:

Treatment with Levothyroxine: Several articles mention the pharmacokinetics, bioavailability, and pregnancy outcomes of levothyroxine, which is a common medication used to treat hypothyroidism.

Autoimmune thyroiditis: Hashimoto's thyroiditis is an autoimmune disorder that can cause hypothyroidism, and several articles focus on its relationship with other conditions, such as hypercholesterolemia and fibrosis.

Thyroid dysfunction and cancer: Some articles discuss the relationship between hypothyroidism and cancer, specifically in the context of immunotherapy and checkpoint inhibitors.

COVID-19 and thyroid hormones: Some articles explore the relationship between COVID-19 and thyroid hormones, suggesting that the virus may affect thyroid function.

New technologies for diagnosis and treatment: Several articles mention new technologies for diagnosing and treating thyroid disorders, such as Vi PLUS shear-wave elastography and HUMIMIC Chip3 for studying thyroid follicles.

To see a more detailed overview of keywords, article descriptions and frequency, see Appendix B1.

Overall, the current trends in hypothyroidism seem to be focused on improving diagnosis and treatment, understanding the relationship between hypothyroidism and other conditions, and exploring the impact of COVID-19 on thyroid function. There is also a focus on developing new technologies to aid in the diagnosis and treatment of thyroid disorders.

KIQ2MG1b

WoS

For the abovementioned search query there were 74760 results from Web of Science Core Collection. The top researchers in this area of expertise are Theo J Visser, Samuel Refetoff and Robin Peeters. Sorting these results by highest citations may provide insight into providing the most relevant articles, therefore the first 50 most cited articles were analyzed.

The top cited article (with 7361 citations) is "2015 American Thyroid Association Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer The American Thyroid Association Guidelines Task Force on Thyroid Nodules and Differentiated Thyroid Cancer" by the authors Haugen, BR; Alexander, EK; Wartofsky, L. This publication discusses the revised guidelines for the management of thyroid nodules and differentiated thyroid cancer, including recommendations for initial evaluation, biopsy criteria, use of molecular markers, management of benign nodules, screening, risk assessment, surgical management, radioiodine therapy, and long-term management. The recommendations are based on published evidence and aim to provide optimal care for patients with these disorders.

Based on the keywords[11] of the top 50 cited articles, a sense of recurring topics can be established: featuring diagnostic and treatment methods (such as whole-body scan and radioiodine remnant ablation), autoimmune disorders of the thyroid (Graves' disease and chronic granulomatous disease), hormone levels and replacement therapy (serum thyroglobulin and stimulating hormone, the use of replacement therapy to treat thyroid disorders) and Cardiovascular and other medical conditions (congestive heart failure, dilated cardiomyopathy, and coronary artery disease). Focusing on the keywords thyroid hormone levels and replacement therapy yielded 6 results[12] (4 articles and 2 reviews), an appraisal of the abstracts of these works revealed the following topics: a cross-sectional study aimed to determine the prevalence of abnormal thyroid function in a large population in the United States and its relationship with lipid levels and symptoms found that the prevalence of abnormal thyroid function was substantial, and even among patients taking thyroid medication, only 60% had normal thyroid-stimulating hormone (TSH) levels[13]; a Whickham Survey followed up on a sample of 2779 adults to determine the incidence and

[11] Key words plus: automatically identified frequently occurring words or phrases that are not included in the article's title or abstract.
[12] Unfortunately, one of the articles did not have an open-access Abstract, thus it was not included in the subsequent topic list.
[13] "The Colorado thyroid disease prevalence study" by Canaris, Manowitz, Mayor, and Ridgway.

natural history of thyroid disease over a 20-year period with results showing higher incidence rates of hypothyroidism in women and negligible rates in men, while hyperthyroidism rates were low in both genders, the study identified risk factors for developing hypothyroidism, including raised serum TSH and positive anti-thyroid antibodies;[14] a review concerning the debate surrounding subclinical thyroid disease (SCTD), which is defined as abnormal serum TSH levels in the presence of normal serum free T-4 and free T-3 levels;[15] a task force reviewed the literature on thyroid hormone replacement therapy and concluded that levothyroxine should remain the standard of care, as there is no consistently strong evidence for the superiority of alternative therapies, and identified several areas for future research[16]; and a review stating that surgical resection followed by adjuvant radioiodine treatment is the primary treatment for most thyroid cancers, with thyroid hormone replacement therapy used to prevent disease recurrence in patients with papillary or follicular carcinomas.[17]

In summary, the literature search yielded six results related to thyroid hormone levels and replacement therapy, highlighting the prevalence of abnormal thyroid function in a large population, the higher incidence rates of hypothyroidism in women, risk factors for developing hypothyroidism, the debate surrounding subclinical thyroid disease, and the use of levothyroxine as the standard of care in thyroid hormone replacement therapy for most patients with thyroid cancer. The identified gaps in research suggest the need for further investigation into alternative therapies and the development of novel approaches for high-risk patients with progressive metastatic disease.

KIQ2MG1a

PubMed

The same search query[18] was performed in PubMed, which brought forth 104774 results. After applying the filter to reveal only the articles published in the last year, there were 3117 results. An effective approach in scientific literature search is to prioritize displaying the latest results, as these papers are frequently accessible on the internet prior to their publication in print, enabling researchers to stay updated with the latest developments. The 10 most recent articles to be published were collected and based on the information in the abstracts the current trends in scientific literature concerning hypothyroidism include the identification of early warning signs of thyroid autoantibodies seroconversion, investigations into the effect of increased dosing of gonadotropins on IVF outcomes, research on the link between thyroid hormones and heart failure after acute myocardial infarction, studies on the effects of quercetin and daidzein on production

[14] “The Incidence of Thyroid-disorders in the community – A 20-year Follow-up of the Whickham Survey“ by Vanderpump, Tunbridge and French.
[15] “The clinical significance of subclinical thyroid dysfunction” by Biondi and Cooper.
[16] The article “Guidelines for the Treatment of Hypothyroidism: Prepared by the American Thyroid Association Task Force on Thyroid Hormone Replacement” by authors Jonklaas, Bianco, and Bauer is from 2014.
[17] “Thyroid carcinoma” by Sherman, Si.
[18] (Hypothyroidism OR levothyroxine OR "C15H11I4NO4" OR "synthetic thyroid hormones" OR thyroxine OR triiodothyronine OR "Hashimoto's thyroiditis" OR "congenital hypothyroidism")

performance in laying hens, investigations into the combined treatment of levothyroxine and testosterone for restoring erectile dysfunction in hypothyroid rats, research on immune-related thyroid dysfunctions during anti PD-1/PD-L1 inhibitors, the analysis of metabolic profiles in women with bulimia nervosa or binge-eating disorder, genetic analysis of children with congenital hypothyroidism, and the alteration of lipid profile between subclinical hypothyroidism and well-matched controls.

KIQ2MG1b

PubMed

Another way to conduct a search for scientific literature pertaining to model group 1 in through the MeSH keyword of levothyroxine. MeSH stands for Medical Subject Headings, which is a controlled vocabulary thesaurus maintained by the National Library of Medicine (NLM) to index and search biomedical literature. MeSH includes standardized terms that are used to describe the subject of an article or other material, making it easier to search for relevant information on a specific topic. MeSH terms are organized in a hierarchical structure, where broader terms encompass more specific ones. This allows for searching a topic at different levels of granularity. Each MeSH term is also associated with a unique identifier (MeSH ID), which allows for more precise searching and avoids ambiguity. When searching PubMed, users can enter MeSH terms that describe the topic they are interested in, and PubMed will retrieve all the articles that are indexed with those terms.

Results for search: PubMed (MeSH Keyword) for id: 5819: 38994 results. MeSH keyword identifier 5819 corresponds to the term "hypothyroidism" in the Medical Subject Headings (MeSH) vocabulary, which is a controlled vocabulary used for indexing and searching biomedical and health-related information in databases such as PubMed. Sorting by best match, the top 10 articles were collected. Based on the abstracts of these articles, there are several emerging trends in the area of thyroid research. One trend involves the use of levothyroxine in the context of cancer treatment. Another trend involves exploring the relationships between thyroid hormones and other hormones or chemicals in the body, such as neuropeptides and blood metals. Additionally, there is interest in the effects of iodine on thyroid health, particularly in pregnant women. Other articles focus on the use of thyroid hormones as potential biomarkers for cancer or the effects of various treatments on thyroid function. Overall, these articles highlight the diverse and multidisciplinary nature of thyroid research, with implications for endocrinology, oncology, obstetrics, and beyond.

In conclusion, the current trends in hypothyroidism are primarily focused on improving diagnosis and treatment, understanding the relationship between hypothyroidism and other conditions, exploring the impact of COVID-19 on thyroid function, and developing new technologies to aid in the diagnosis and treatment of thyroid disorders. A scientific literature search in Web of Science and PubMed was conducted, and by analyzing the publications from 2023 and top-cited or best-matched articles, it was possible to identify the most relevant topics. The top cited article discusses the revised guidelines for the management of thyroid nodules and differentiated thyroid cancer, including recommendations for initial evaluation, biopsy criteria, use of molecular markers, management of benign nodules, screening, risk assessment, surgical management,

radioiodine therapy, and long-term management. The current trends in hypothyroidism seem to be focused on improving diagnosis and treatment, understanding the relationship between hypothyroidism and other conditions, exploring the impact of COVID-19 on thyroid function, and developing new technologies to aid in the diagnosis and treatment of thyroid disorders, based on an analysis of publications from 2023. Overall, the research in this field is focused on providing optimal care for patients with thyroid disorders.

5.2 Model group 2 - NSAIDs

The second category comprises non-steroidal anti-inflammatory drugs (NSAIDs), which are a commonly used medication group to alleviate pain and reduce inflammation. They function by impeding the production of prostaglandins, which are chemicals involved in the inflammation and pain process. NSAIDs are accessible over the counter or by prescription and can be ingested orally or applied topically to the skin. Examples of NSAIDs include ibuprofen, diclofenac, and naproxen. Analgesics, also known as painkillers, are a class of medications that are used to relieve pain. They function by either blocking pain signals from being transmitted to the brain or interfering with the brain's perception of pain. Analgesics can be classified into two primary groups: non-opioid analgesics such as paracetamol and NSAIDs, and opioid analgesics, which are more potent painkillers that are typically only prescribed for severe pain. NSAIDs can be categorized based on their chemical structure, the main categories of NSAIDs are salicylates, propionic acid derivatives, acetic acid derivatives, COX-2 inhibitors (Ghlichloo, 2022).

- Salicylates: This category includes aspirin, which is one of the oldest and most commonly used NSAIDs. Salicylates are derived from salicylic acid and work by inhibiting the production of prostaglandins (Ghlichloo, 2022).
- Propionic acid derivatives: This category includes ibuprofen and naproxen, which are commonly used to relieve pain and inflammation. Propionic acid derivatives work by inhibiting the production of prostaglandins (Ghlichloo, 2022).
- Acetic acid derivatives: This category includes indomethacin and sulindac, which are typically used for the treatment of rheumatoid arthritis and other inflammatory conditions. Acetic acid derivatives also work by inhibiting the production of prostaglandins (Ghlichloo, 2022).
- COX-2 inhibitors: This category includes celecoxib, which is a newer type of NSAID that selectively inhibits the COX-2 enzyme. COX-2 inhibitors are typically used to treat arthritis and other inflammatory conditions, but they may have a higher risk of causing cardiovascular side effects compared to other types of NSAIDs (Ghlichloo, 2022).

The use of medication to relieve pain and inflammation has a long history dating back to ancient civilizations such as the Greeks and Romans who used plant extracts such as willow bark to alleviate pain. However, the development of modern NSAIDs began in the late 19th century when chemists started synthesizing salicylic acid, the active ingredient in willow bark, and testing its effects. In 1897, a German chemist named Felix Hoffmann discovered that acetylsalicylic acid, also known as aspirin, could relieve pain and reduce

fever without the negative side effects of salicylic acid. Aspirin quickly became a popular medication for pain relief and is still widely used today. Other types of NSAIDs were developed in the following decades, with the first propionic acid derivative, ibuprofen, being synthesized in the 1960s. Naproxen, another propionic acid derivative, was developed in the 1970s and became popular for its longer-lasting effects. COX-2 inhibitors, such as celecoxib, were developed in the 1990s and were marketed as having fewer gastrointestinal side effects than traditional NSAIDs (Montinari, 2018). However, studies later found that COX-2 inhibitors may increase the risk of cardiovascular events, leading to some of them being withdrawn from the market or receiving warning labels (Howes, 2007). Overall, the development of NSAIDs has been a significant milestone in the history of pain relief and has provided individuals with a variety of options for managing pain and inflammation.

Commonly used NSAIDs in Europe and the United States are similar, although there may be some differences in availability and popularity. Different NSAIDs may be preferred for different types of pain or medical conditions, and individual responses to NSAIDs may also vary. Therefore, even though this medication is not regulated, it is still advised to consult with a healthcare professional before starting any new medication.

The TI process for Model Group 2 was essentially the same as for Model Group 1. After defining the scope of the model group and then confirming the KITs and KIQs, creating the keywords and collecting the data, cleaning the data, it was time for analyses. For model group 2, the keywords were: Nonsteroidal anti-inflammatory drugs, COX inhibitors, cyclooxygenase inhibitors, Pain relief, Anti-inflammatory drugs, Analgesics, NSAID, Ibuprofen, aspirin, acetylsalicylic acid, naproxen, diclofenac. A more detailed account of the keyword creation can be found in Appendix B2. However, the search and analyses were divided into two: one for topical administration with the IPC codes A61K31/415 and A61K31/416 and one for per oral administration of NSAIDs, IPC code A61K 31/19, which covers oral preparations containing organic active ingredients.

Using the refined keywords, a search was conducted on the PatentScope database using the following query:

Precision version 1

((EN_TI:"Nonsteroidal anti-inflammatory drugs") OR (EN_AB:"Nonsteroidal anti-inflammatory drugs") OR (EN_CL:"Nonsteroidal anti-inflammatory drugs") OR (EN_TI:"COX inhibitors") OR (EN_AB:"COX inhibitors") OR (EN_CL:"COX inhibitors") OR (EN_TI:"cyclooxygenase inhibitors") OR (EN_AB:"cyclooxygenase inhibitors") OR (EN_CL:"cyclooxygenase inhibitors") OR (EN_TI:"Pain relief") OR (EN_AB:"Pain relief") OR (EN_CL:"Pain relief") OR (EN_TI:"Anti-inflammatory drugs") OR (EN_AB:"Anti-inflammatory drugs") OR (EN_CL:"Anti-inflammatory drugs") OR (EN_TI:"Analgesics") OR (EN_AB:"Analgesics") OR (EN_CL:"Analgesics") OR (EN_TI:NSAID) OR (EN_AB:NSAID) OR (EN_CL:NSAID) OR (EN_TI:Ibuprofen) OR (EN_AB:Ibuprofen) OR (EN_CL:Ibuprofen) OR (EN_TI:aspirin) OR (EN_AB:aspirin) OR (EN_CL:aspirin) OR (EN_TI:"acetylsalicylic acid") OR (EN_AB:"acetylsalicylic acid") OR (EN_CL:"acetylsalicylic acid") OR (EN_TI:naproxen) OR (EN_AB:naproxen) OR (EN_CL:naproxen) OR (EN_TI:diclofenac) OR (EN_AB:diclofenac) OR (EN_CL:diclofenac)) AND ((CPC:"A61K31/415") OR (CPC:"A61K31/416"))

This Precision search yielded 2075 results. The patent code A61K31/416 refers to a specific classification code used by the World Intellectual Property Organization for patents related to pharmaceutical compositions. This particular code refers to "medicinal preparations containing organic active ingredients" with "heterocyclic compounds having sulfur as a ring hetero atom" as the active ingredient. Essentially, it describes pharmaceutical compositions that contain a specific class of sulfur-containing heterocyclic compounds as their active ingredient. The patent code A61K31/415 refers to heterocyclic compounds containing two or more hetero rings, which include at least one nitrogen atom and one sulfur atom. These compounds have potential therapeutic applications. Both A61K31/416 and A61K31/415 are suitable for NSAIDs. They are subcategories of the main category A61K31, which pertains to therapeutic agents. Specifically, A61K31/416 relates to the use of non-specific cyclooxygenase inhibitors, while A61K31/415 pertains to the use of specific cyclooxygenase-2 inhibitors. Since NSAIDs work by inhibiting cyclooxygenase enzymes, both of these patent codes can be applicable to NSAID formulations.

Precision version 2

((EN_TI:"Nonsteroidal anti-inflammatory drugs") OR (EN_AB:"Nonsteroidal anti-inflammatory drugs") OR (EN_CL:"Nonsteroidal anti-inflammatory drugs") OR (EN_TI:"COX inhibitors") OR (EN_AB:"COX inhibitors") OR (EN_CL:"COX inhibitors") OR (EN_TI:"cyclooxygenase inhibitors") OR (EN_AB:"cyclooxygenase inhibitors") OR (EN_CL:"cyclooxygenase inhibitors") OR (EN_TI:"Pain relief") OR (EN_AB:"Pain relief") OR (EN_CL:"Pain relief") OR (EN_TI:"Anti-inflammatory drugs") OR (EN_AB:"Anti-inflammatory drugs") OR (EN_CL:"Anti-inflammatory drugs") OR (EN_TI:"Analgesics") OR (EN_AB:"Analgesics") OR (EN_CL:"Analgesics") OR (EN_TI:NSAID) OR (EN_AB:NSAID) OR (EN_CL:NSAID) OR (EN_TI:Ibuprofen) OR (EN_AB:Ibuprofen) OR (EN_CL:Ibuprofen) OR (EN_TI:aspirin) OR (EN_AB:aspirin) OR (EN_CL:aspirin) OR (EN_TI:"acetylsalicylic acid") OR (EN_AB:"acetylsalicylic acid") OR (EN_CL:"acetylsalicylic acid") OR (EN_TI:naproxen) OR (EN_AB:naproxen) OR (EN_CL:naproxen) OR (EN_TI:diclofenac) OR (EN_AB:diclofenac) OR (EN_CL:diclofenac)) AND (CPC:"A61K31/19")

Search results: 11340. The code A61K31/19 refers to the subgroup of non-steroidal anti-inflammatory drugs (NSAIDs) that have an acetic acid derivative structure, such as aspirin, ibuprofen, and naproxen. This code is relevant to NSAIDs because it is used to classify drugs based on their chemical structure and therapeutic use. As mentioned above, NSAIDs work by inhibiting the activity of cyclooxygenase (COX) enzymes, which are involved in the production of prostaglandins, a type of hormone-like substance that promotes inflammation, pain, and fever. NSAIDs are commonly used to relieve pain, inflammation, and fever, and they are often used to treat conditions such as arthritis, menstrual cramps, headaches, and other types of pain. In comparison to the code used to obtain the dataset Precision version 1, the CPC code A61K31/19 refers to the use of NSAIDs in general, regardless of their formulation or method of administration.

Recall

((EN_TI:"Nonsteroidal anti-inflammatory drugs") OR (EN_AB:"Nonsteroidal anti-inflammatory drugs") OR (EN_CL:"Nonsteroidal anti-inflammatory drugs") OR

(EN_TI:"COX inhibitors") OR (EN_AB:"COX inhibitors") OR (EN_CL:"COX inhibitors") OR (EN_TI:"cyclooxygenase inhibitors") OR (EN_AB:"cyclooxygenase inhibitors") OR (EN_CL:"cyclooxygenase inhibitors") OR (EN_TI:"Pain relief") OR (EN_AB:"Pain relief") OR (EN_CL:"Pain relief") OR (EN_TI:"Anti-inflammatory drugs") OR (EN_AB:"Anti-inflammatory drugs") OR (EN_CL:"Anti-inflammatory drugs") OR (EN_TI:"Analgesics") OR (EN_AB:"Analgesics") OR (EN_CL:"Analgesics") OR (EN_TI:NSAID) OR (EN_AB:NSAID) OR (EN_CL:NSAID) OR (EN_TI:Ibuprofen) OR (EN_AB:Ibuprofen) OR (EN_CL:Ibuprofen) OR (EN_TI:aspirin) OR (EN_AB:aspirin) OR (EN_CL:aspirin) OR (EN_TI:"acetylsalicylic acid") OR (EN_AB:"acetylsalicylic acid") OR (EN_CL:"acetylsalicylic acid") OR (EN_TI:naproxen) OR (EN_AB:naproxen) OR (EN_CL:naproxen) OR (EN_TI:diclofenac) OR (EN_AB:diclofenac) OR (EN_CL:diclofenac)) AND (IC:"A61K*")

The Recall search yielded 73549 results, 10000 of which could be analyzed, as PatentScope only allows to download up to 10000 results. These results were sorted by relevance. Results from both Precision and Recall searches were downloaded into Excel files and then connected to Tableau.

KIQ1MG2 (The Key Intelligence Question 1 for Model Group 2): Who are the main competitors in the field, and in which territories are they seeking patent protection?

The data from the Precision version 1 dataset shows that the top three applicants with the most patents are: Esteve, Pfizer (Pharmacia Corporation), and Merck.

Laboratorios del Dr. ESTEVE, S.A. is a Spanish pharmaceutical company founded in 1929 by Dr. Antoni Esteve i Subirana. As of 2021, Esteve employs over 1500 people and has net revenues of 550 million euros (Esteve, 2023).

Pharmacia Corporation was a global pharmaceutical company that specialized in developing and manufacturing prescription drugs, as well as consumer health products. It was involved in one of the largest corporate mergers in history when it merged with Pfizer in 2003 (Pfizer, 2023).

Esteve has 110 patents in the following countries: Esteve has 1 patent each in Bulgaria, Czech Republic, Philippines, and Serbia, and 2 patents in Japan and Portugal. It has 3 patents each in New Zealand and Tunisia, 4 patents each in Denmark and Spain, and 6 patents each in Mexico and Singapore. It has 8 patents each in Australia and China, and 13 patents in Canada. Esteve has 17 patents in Europe (EP) and 25 patents in the World Intellectual Property Organization (WO).

Pfizer has 78 patents: Pfizer has 1 patent each in Denmark, United Kingdom, Israel, and Japan, and 3 patents each in Poland and the United States. It has 4 patents in China, 6 patents each in New Zealand, South Africa, and the World Intellectual Property Organization (WO), and 11 patents in Europe (EP). Pfizer has 14 patents in Australia and 21 patents in Canada.

Merck has 4 patents in Australia, 5 patents in Canada, and 6 patents in the United States. It has 14 patents in Europe (EP) and 15 patents in the World Intellectual Property Organization (WO).

In this dataset, the top five territories are: WO (473 patents), US (411), EP (282), CA (272) and AU (228). The most patent active inventors were Vuong Trieu with 8 patents (applied under Autotelic LLC). The duo Ruey J. Yu and Eugene J. Van Scott have 7 patents (6 applied under Tristrata Technology, Inc. and 1 under their own names) and Antonio Torrens Jover and Susana Yenes Minguez have 6 patents (applied under Esteve).

The top three applicants from the Precision version 2 dataset were Wellesley Pharmaceuticals LLC with 134 patents (with the top three countries being US 37, WO 18, AU 15), Reckitt Benckiser Health Limited with 115 patents (EP 19, WO 18, AU 16) and Hisamitsu Pharmaceutical Co., Inc. with 95 patents (EP 24, WO 23, US 14). For this dataset the top three countries without regarding the applicants were US 2265, WO 2021 and EP 1320.

Wellesley Pharmaceuticals LLC is a pharmaceutical company based in the United States. The company focuses on the development and commercialization of innovative prescription and over-the-counter (OTC) pharmaceutical products for pain management, cough and cold, and other related areas. Wellesley Pharmaceuticals LLC was founded in 2013 and is headquartered in Fort Washington, Pennsylvania (Wellesley, 2023).

Reckitt Benckiser Health Limited is a British multinational consumer goods company that specializes in health, hygiene, and home products. The company is a subsidiary of Reckitt Benckiser Group plc and is based in Slough, UK. Reckitt Benckiser Health Limited produces and markets a range of well-known healthcare brands, including Nurofen, Strepsils, Gaviscon, Durex, and Clearasil, among others (Reckitt Benckiser, 2023).

Hisamitsu Pharmaceutical Co., Inc. is a Japanese pharmaceutical company that specializes in the development and manufacturing of transdermal therapeutic systems and topical medications. The company was founded in 1847 in Saga, Japan, and has since expanded globally (Hisamitsu, 2023).

In the Recall dataset for MG2 the results for top applicants were Purdue Parma (199 patents[19]), Bayer Pharma (102 patents), McNeil PPC INC (97 patents). As for the territory of these patents, the top three for each applicant are Purdue Pharma (US 82, EP 41, AU 19), Bayer (US 22, WO 17, CA 16) and McNeil (AU 21, US 17, CA 16).

[19] Of which EURO-CELTIQUE S.A. (124 patents). Euro-Celtique S.A. was a pharmaceutical company that focused on developing and marketing pain management drugs. The company was established in 1993 and was headquartered in Luxembourg. Its flagship product was OxyContin, a long-acting painkiller that was subject to widespread controversy due to its addictive properties. Euro-Celtique was eventually acquired by Purdue Pharma in 2014.

Purdue Pharma is a pharmaceutical company that was founded in 1892 and is based in Stamford, Connecticut. The company is known for its development of pain medications (Purdue, 2023).

Bayer Pharma is the pharmaceutical division of Bayer AG, a multinational chemical and pharmaceutical company based in Germany. The division is responsible for developing and manufacturing a wide range of pharmaceutical products, including prescription drugs, over-the-counter medications, and medical devices. Bayer Pharma's focus areas include cardiology, women's health, hematology, oncology, and ophthalmology (Bayer, 2023).

McNeil PPC Inc. is a subsidiary of Johnson & Johnson that develops and markets a range of consumer healthcare products, including over-the-counter medications, dietary supplements, and medical devices. The company was founded in 1879 and was acquired by Johnson & Johnson in 1959 (Jnj, 2023). McNeil PPC Inc. is best known for its brand Tylenol.

When looking at the countries, the top five are: US 3437 patents, WO 1530 patents, EP 1232 patents, CA 931 patents and AU 921 Patents. In comparison, the Precision version 1 dataset's top countries were WO 473, US 411, EP 282, CA 272 and AU 228 patents. From the data provided by PatentScope, it can be concluded that the top three territories where applicants are seeking patent protection for the second model group of pharmaceuticals are US, WO and EP.

Note from the author: Scopus also has the option of filtering patents, using the same search query[20] that was used find scientific literature to answer the second Key Intelligence Question and limiting the results to the year 2023, this search provided 5387 patents. The countries (or rather Patent offices) are US (USPTO, 3581 patents), JP (JPO, 1085), EP (EPO, 377), WO (WIPO, 329) and GB (UKIPO, 15). This seems to be in line with the patent strategy of most companies, that involves seeking patent protection in multiple territories around the world to prevent competitors from entering the market with generic versions of their drugs. This often includes seeking patent protection in the United States, WO and Europe.

KIQ2MG2: What are the current development trends within this model group?

To answer this Key Intelligence Question, a scientific literature search was conducted in Web of Science and Scopus. The search query below yielded 271646 results in Wos. In Scopus[21] the number of results was 628015.

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[20] TITLE-ABS-KEY (("Nonsteroidal anti-inflammatory drugs" OR "COX inhibitors" OR "cyclooxygenase inhibitors" OR "Pain relief" OR "Anti-inflammatory drugs" OR analgesics OR nsaid OR ibuprofen OR aspirin OR "acetylsalicylic acid" OR naproxen OR diclofenac)) AND ((PUBYEAR = 2023))

[21] Scopus search query: TITLE-ABS-KEY (("Nonsteroidal anti-inflammatory drugs" OR "COX inhibitors" OR "cyclooxygenase inhibitors" OR "Pain relief" OR "Anti-inflammatory drugs" OR analgesics OR nsaid OR ibuprofen OR aspirin OR "acetylsalicylic acid" OR naproxen OR diclofenac))

Search query:

TS=("Nonsteroidal anti-inflammatory drugs" OR "COX inhibitors" OR "cyclooxygenase inhibitors" OR "Pain relief" OR "Anti-inflammatory drugs" OR Analgesics OR NSAID OR Ibuprofen OR aspirin OR "acetylsalicylic acid" OR naproxen OR diclofenac)

Similarly, as with MG1, using the filters available in WoS to refine this search by publication year, it was possible conduct one analysis of the dataset of the publications refined as from 2023 (KIQ2MG2a) and the other concerning the top cited articles regardless of the publication year (KIQ2MG2b).

KIQ2MG2a

WoS

Within the publications from 2023, there were 2904 publications this year and the top 10 research areas were:

Figure 10 WoS TreeMap Chart of Research areas of the given search (KIQ2MG2a), by the Author

When reviewing the articles from the Pharmacology Pharmacy research area, based on the provided author keywords and abstracts of the articles, it is possible to identify some current trends related to NSAIDs:

Molecular modeling: There are studies using molecular modeling to explore the COX (cyclooxygenase) enzyme and its interaction with NSAIDs such as ibuprofen, indomethacin, and diclofenac.

Toxicity and side effects: There are studies investigating the potential gastrointestinal, renal, and hepatotoxicity of NSAIDs, as well as their impact on oxidative stress biomarkers and liver pathology. Other studies explore the interactions between NSAIDs and other drugs, such as losartan and atorvastatin, and the impact on the gut microbiota and cardiovascular disease.

Novel drug delivery systems: There are studies investigating the use of buccal tablets, lipid vesicles, and pH-sensitive microbeads for delivering diclofenac sodium.

Biodegradation: There are studies exploring the biodegradation of NSAIDs by defined bacterial consortiums or individual bacteria.

Multi-target drugs: There are studies investigating the potential of multi-target drugs that target both COX and HDAC (histone deacetylase) enzymes or TRPV1 (transient receptor potential vanilloid type 1) and mu-opioid receptors for pain relief.

Natural products: There are studies exploring the analgesic and anti-inflammatory effects of natural products such as ginger, Rhododendron dauricum, Euphorbia larica, and Anoectochilus elatus.

Designing NSAIDs: Some articles mention the use of asymmetric catalysis and Lewis acids for the design and synthesis of new NSAIDs.

Targeted drug delivery: Several articles discuss targeting drug delivery systems for NSAIDs, including dual-response systems and Achyranthes polysaccharide and celastrol-based systems.

NSAIDs and pain management: Many articles focus on the mechanism of action of NSAIDs in pain management, including descending noradrenergic inhibition, norepinephrine transporter, serotonin and norepinephrine reuptake, synaptic plasticity, tricyclic antidepressants, and MRGPRX1 receptor.

NSAIDs and inflammation: Several articles discuss the anti-inflammatory properties of NSAIDs, including their effects on basophils, mast cells, neutrophils, and inflammation-related pathways such as Akt, NF-kappa B, and Nrf2.

Natural products and NSAIDs: Some articles explore natural products, including Salvinorin A, salvianolic acid B, Thymol, and Withania somnifera, and their potential use in combination with NSAIDs for pain relief.

NSAIDs and diseases: Some articles focus on the potential use of NSAIDs in treating various diseases such as rheumatoid arthritis, osteoarthritis, sepsis, and cancer.

Drug delivery systems for NSAIDs: Some articles discuss drug delivery systems for NSAIDs, including long-acting injectables, nanostructured lipid carriers, expandable film, and solid dispersion.

Other topics: Other topics related to NSAIDs include wound healing, antibacterial and antioxidant activities, removal of NSAIDs from wastewater, and the use of NSAIDs in the treatment of liver injury. There are studies investigating various other topics related to NSAIDs, such as herb-drug interactions, nanoparticle drug delivery systems, and the impact of NSAIDs on the gonadal transcriptome, brain fog, and migraines.

Overall, the trends suggest a focus on designing and developing new NSAIDs, targeting drug delivery systems and exploring natural products as potential adjuvants for pain management. To see a more detailed overview of keywords and frequency, see Appendix B2.

Scopus

The Scopus search generated 628015 results in total, 8316 of which were published in 2023. 149 of the 2023 articles had an affiliation with Harvard Medical School, 121 with the Ministry of Education China and 84 with the University of Toronto. The main funding sponsors behind the articles from 2023 were the National Natural Science Foundation of China (581 documents), the NIH (402 documents) and the National Institute of Drug Abuse (141 documents). The top three authors regarding publication quantity were Angiolillo, D.J. (12 documents), Woods, R.L. (also 12 documents) and Malas, M.B. (11 documents). The most frequent notable keywords of these documents were: Human/humans (5638/4314), Female (3278), Male (3160), Controlled Study (2514) and Acetylsalicylic Acid (2057). 1170 documents were from the subject area Pharmacology, Toxicology and Pharmaceutics. Further limiting the search to only include open access documents narrowed the selection to 508 documents, using the filtering by the keyword "review" option[22], the results were reduced to 57 documents, that were then downloaded in CSV format and further analyzed. After reviewing the abstracts of these documents (for a more in depth review of the first 20 articles from this dataset see Appendix B2) and noticing a frequent appearance of "opioid" within the subject matter, the search was altered to exclude "opioid" from the results:

TITLE-ABS-KEY (("Nonsteroidal anti-inflammatory drugs" OR "COX inhibitors" OR "cyclooxygenase inhibitors" OR "Pain relief" OR "Anti-inflammatory drugs" OR analgesics OR nsaid OR ibuprofen OR aspirin OR "acetylsalicylic acid" OR naproxen OR diclofenac AND NOT "Opioid")) AND (LIMIT-TO (OA , "all")) AND (LIMIT-TO (SUBJAREA , "PHAR")) AND (LIMIT-TO (PUBYEAR , 2023))

The search gathered 427 documents and when limiting to "Review", there were 43 documents, that were then analyzed. From the abstracts of these documents, keywords were extracted, and topics were summarized (see Appendix B for full analysis). Based on the keywords and summaries, there are a few promising trends in the area. There are several current trends in NSAID research, including drug delivery systems, personalized medicine, and the treatment of diseases like cancer, spinal cord injury, and heart failure. Another focus is on the phytochemical constituents and biological activities of plants that may have anti-inflammatory properties. Researchers are also investigating the modulation of inflammatory responses and the development of pharmacological interventions and therapies for CNS disorders. The COVID-19 pandemic has had a significant impact on healthcare, and researchers are exploring how NSAIDs can be used in pandemic

[22] "Review" typically refers to an article that summarizes and synthesizes information from multiple sources, rather than presenting original research. However, a review article can still be a good choice for learning about current development trends within NSAIDs, as it can provide an overview of recent research and highlight areas of ongoing investigation. Additionally, many review articles also include original data analysis or perspectives on the field, which can provide valuable insights.

management. Finally, there is a growing interest in nanomedicine and nanocarriers as delivery systems for NSAIDs.

KIQ2MG2b

Scopus

The original Scopus search was altered[23] to exclude opioid results, going from 628015 results to 547846 results. Sorting the results by most cited and assessing the first ten results gave insight to relevant topics within this area. The most cited article, with 12945 citations, focuses on heart rate variability. However, this article is from the year 1996. While the information in this article may still be relevant, it will hardly lead to answers concerning the KIQ. For that reason, it was prudent to filter the results for a more current time frame.

The timeframe for the articles within consideration when searching for scientific literature to answer KIQs with trend like subject matter will vary depending on the topic and the pace of developments in that particular field. Generally, it is a good idea to consider the most recent publications, so a timeframe of the past 2-3 years is often a good starting point for current trends. However, if the topic is a rapidly developing field, it may be necessary to narrow the search to the past year or even the past 6 months to capture the most up-to-date information. For a topic like NSAIDs, which has been extensively studied for many years, a good timeframe for searching for current trends would be the past 3-5 years. This would ensure the most up-to-date information and recent advancements in the field but also a good overview of the topic. In light of the current climate and the dominance of the COVID-19 pandemic in 2020, it is noteworthy that the majority of highly cited articles (6 out of the 10 top cited articles in the given timeframe from 2020) pertain to the COVID-19 topic, which may not be directly pertinent to contemporary trends regarding NSAIDs, although the significance of COVID-19 as a subject of inquiry remains considerable and is likely to endure. For that reason results were filtered to the range 2021-2023.

The top ten cited articles were concerned with various topics, some of the articles discussed the safety and efficacy of certain NSAIDs compared to others, suggesting that safety and side effect concerns are still an important topic in the field. Additionally, the use of NSAIDs for pain management in various medical conditions was a recurring theme. COVID-19 was like a recurring topic, one article discussed the potential use of NSAIDs in COVID-19 patients and suggested that caution should be exercised due to the possible risk of adverse effects. Another article discussed the potential for NSAIDs to be used as a treatment option for COVID-19, based on the anti-inflammatory properties of these drugs.

Patent analysis

A dataset consisting of the latest Patents by Date Published Descending was obtained from PatentScope and the abstracts of the 10 most recently published patents were examined.

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[23] "Nonsteroidal anti-inflammatory drugs" OR "COX inhibitors" OR "cyclooxygenase inhibitors" OR "Pain relief" OR "Anti-inflammatory drugs" OR analgesics OR nsaid OR ibuprofen OR aspirin OR "acetylsalicylic acid" OR naproxen OR diclofenac AND NOT opioid

One abstract described a new type of photocleavable prodrug that can be activated by light, enabling controllable drug delivery to target sites with high loading capacity and efficient activation, using a boron-dipyrromethene-derived prodrug and a dye for stabilization, tumor targeting, and in-situ monitoring of nanoparticle dissociation. Another described the use of polypeptides and related compounds to stimulate the ERK signaling pathway in the brain as a potential treatment for neurodegenerative or neuropsychiatric disorders and cognitive impairment. One patented product provides fast pain relief and cooling comfort for various conditions including arthritis pain, joint discomfort, muscle soreness, and foot pain. One describes the use of a quinoline compound or its salt for treating ARDS, viral infections, and other diseases, disorders, and conditions. The following patent describes methods of preventing or treating infection by a SARS-CoV-related betacoronavirus using a small molecule drug, an antibody that binds to ACE2-SARS interaction domain, or vaccines comprising S-protein polypeptides corresponding to the ACE-2 interaction domain. Another invention relates to a method of treating pneumonia in a patient by administering an effective amount of an IL-6 antagonist to a patient identified as having elevated ferritin levels, to achieve an improved clinical response and reduced time to hospital discharge. The next abstract described methods and compositions for treating or preventing viral infections, including SARS-CoV-2, using adjuvants delivered to individuals receiving or having received fibroblasts or fibroblast-derived exosomes. The next invention describes a multimodal antiemetic anesthetic/analgesic formulation for pain control, comprising a local anesthetic, an N-methyl-D-aspartate (NMDA) receptor antagonist, and a cyclooxygenase (COX) inhibitor that reduces postoperative nausea and vomiting and enhances pain relief. The ensuing invention is related to using ampakines for treating central nervous system disorders, including attention deficit disorders and related conditions. The tenth patent describes the use of ammonia oxidizing microorganisms to treat urogenital and inflammatory disorders through various methods including administration via devices and kits.

Based on the information provided from the abstracts of the patents summarized above, it is difficult to discern overarching trends in the field of pharmaceuticals or medicine as a whole. However, several specific developments in drug discovery and treatment are described, including novel drug delivery systems, potential treatments for neurodegenerative and neuropsychiatric disorders, pain management formulations, treatments for viral infections such as SARS-CoV-2, and the use of ammonia oxidizing microorganisms for treating urogenital and inflammatory disorders.

5.3 Model group 3 – anticancer drugs

The knowledge of the molecular and genetic basis of cancer has led to the development of various types of anticancer drugs, each targeting specific abnormalities associated with cancer development and progression. Targeted therapies are a group of anticancer drugs that aim to target specific molecules or pathways involved in cancer cell growth and development. Monoclonal antibodies, for instance, are proteins that attach to specific molecules on the surface of cancer cells, while tyrosine kinase inhibitors block enzymes called tyrosine kinases that play a role in promoting cancer cell growth and

survival. Immunotherapies, another group of anticancer drugs, are designed to enhance the body's immune system's ability to recognize and attack cancer cells (Mansoori, 2017). Examples of immunotherapies include checkpoint inhibitors, which block molecules on immune cells that cancer cells use to evade the immune system, and cancer vaccines that stimulate the immune system to recognize and attack cancer cells.

The TI process for Model Group 3 was again principally unchanged as for the previous model groups, although two sets of datasets were acquired for both Precision and Recall searches, one set focusing specifically on CAR T-cell therapy and one set not having this distinction. After defining the scope of the model group, then confirming the KITs and KIQs, creating the keywords, collecting and cleaning the data, it was time for analyses. For Model Group 3, the keywords were: cancer treatment, targeted therapies, molecular targets, genetic targets, monoclonal antibodies, tyrosine kinase inhibitors, immunotherapies, checkpoint inhibitors, cancer vaccines. Using these keywords, a search was conducted on the PatentScope database using the following queries:

Precision CAR T-cell therapy

((EN_TI:" genetically modified T lymphocytes") OR (EN_AB:" genetically modified T lymphocytes") OR (EN_CL:" genetically modified T lymphocytes") OR (EN_TI:" CAR T-cell therapy") OR (EN_AB:"CAR T-cell therapy") OR (EN_CL:" CAR T-cell therapy")) AND ((CPC:"A61K31/16") OR (CPC:"A61K31/17") OR (CPC:"A61K31/18") OR (CPC:“A61K38/00”))

155 results

CAR T-cell therapy (Chimeric Antigen Receptor T-cell therapy) is a type of immunotherapy used to treat certain types of cancer. It involves collecting T cells (a type of white blood cell) from a patient's blood and modifying them in a laboratory so that they can recognize and attack cancer cells (American Cancer Society, 2023). This is done by genetically engineering T cells to produce special receptors called chimeric antigen receptors (CARs) on their surface. These CARs allow the T cells to recognize specific proteins on the surface of cancer cells, triggering an immune response that destroys the cancer cells. Once the CAR T cells have been modified and multiplied in the lab, they are infused back into the patient's bloodstream, where they travel to the site of the cancer and attack it. CAR T-cell therapy is a highly personalized treatment, as the CARs are designed to target the specific cancer cells of each patient (American Cancer Society, 2023). CAR T-cell therapy has shown remarkable success in treating certain blood cancers, such as leukemia and lymphoma, with high response rates and long-lasting remissions in some patients (Jogalekar, 2022). However, it can also cause serious side effects, such as cytokine release syndrome (CRS) and neurotoxicity, which require careful monitoring and management.

The IPC code for cancer treatment drugs is A61K 31/16, A61K 31/17, and A61K 31/18, which all relate to the use of chemical compounds or compositions for the treatment of cancer. The IPC code for cancer treatment methods is A61K 38/00, which relates to the use of biological substances, such as proteins or antibodies, for the treatment of cancer. Therefore, a combination of both IPC codes could be used for a comprehensive search of cancer treatment patents.

Precision ALL

((EN_TI:"cancer treatment") OR (EN_AB:"cancer treatment") OR (EN_CL:"cancer treatment") OR (EN_TI:"targeted therapies") OR (EN_AB:"targeted therapies") OR (EN_CL:"targeted therapies") OR (EN_TI:"molecular targets") OR (EN_AB:"molecular targets") OR (EN_CL:"molecular targets") OR (EN_TI:"genetic targets") OR (EN_AB:"genetic targets") OR (EN_CL:"genetic targets") OR (EN_TI:"monoclonal antibodies") OR (EN_AB:"monoclonal antibodies") OR (EN_CL:"monoclonal antibodies") OR (EN_TI:"tyrosine kinase inhibitors") OR (EN_AB:"tyrosine kinase inhibitors") OR (EN_CL:"tyrosine kinase inhibitors") OR (EN_TI:"immunotherapies") OR (EN_AB:"immunotherapies") OR (EN_CL:"immunotherapies") OR (EN_TI:"checkpoint inhibitors") OR (EN_AB:"checkpoint inhibitors") OR (EN_CL:"checkpoint inhibitors") OR (EN_TI:"cancer vaccines") OR (EN_AB:"cancer vaccines") OR (EN_CL:"cancer vaccines")) AND ((CPC:"A61K31/16") OR (CPC:"A61K31/17") OR (CPC:"A61K31/18") OR (CPC:“A61K38/00”))

17235 results

Recall CAR T-cell therapy

((EN_TI:" genetically modified T lymphocytes") OR (EN_AB:" genetically modified T lymphocytes") OR (EN_CL:" genetically modified T lymphocytes") OR (EN_TI:" CAR T-cell therapy") OR (EN_AB:"CAR T-cell therapy") OR (EN_CL:" CAR T-cell therapy")) AND (CPC:"A61K*")

724 results

Recall ALL

((EN_TI:"cancer treatment") OR (EN_AB:"cancer treatment") OR (EN_CL:"cancer treatment") OR (EN_TI:"targeted therapies") OR (EN_AB:"targeted therapies") OR (EN_CL:"targeted therapies") OR (EN_TI:"molecular targets") OR (EN_AB:"molecular targets") OR (EN_CL:"molecular targets") OR (EN_TI:"genetic targets") OR (EN_AB:"genetic targets") OR (EN_CL:"genetic targets") OR (EN_TI:"monoclonal antibodies") OR (EN_AB:"monoclonal antibodies") OR (EN_CL:"monoclonal antibodies") OR (EN_TI:"tyrosine kinase inhibitors") OR (EN_AB:"tyrosine kinase inhibitors") OR (EN_CL:"tyrosine kinase inhibitors") OR (EN_TI:"immunotherapies") OR (EN_AB:"immunotherapies") OR (EN_CL:"immunotherapies") OR (EN_TI:"checkpoint inhibitors") OR (EN_AB:"checkpoint inhibitors") OR (EN_CL:"checkpoint inhibitors") OR (EN_TI:"cancer vaccines") OR (EN_AB:"cancer vaccines") OR (EN_CL:"cancer vaccines")) AND (IC:"A61K*")

120118 results

For the searches yielding over 10000 results, only 10000 results could be analyzed, as PatentScope only allows the downloading of up to 10000 results. These results were sorted by relevance. Results from both Precision and Recall searches were downloaded into Excel files and then connected to Tableau.

KIQ1MG3 (The Key Intelligence Question 1 for Model Group 3): Who are the main competitors in the field, and in which territories are they seeking patent protection?

The data from the Precision All dataset shows that the top three applicants with the most patents are: Immatics Biotechnologies, Genentech and The Regents of the University of California.

Immatics(432 patents)	Genentech (166)	The Regents of the University of California (120)
United States (106)	US (37)	WO (49)
European Patent (EP) (68)	WO (30)	US (39)
Canada (57)	CA (28)	CA (14)
Australia (55)	EP (24)	AU (11)
China (36)	NZ (5)	IL (2)
Japan (32)	CN (3)	NZ (2)
Singapore (22)	ZA (2)	PT (1)
WO (17)	SG (2)	CZ (1)
Costa Rica (16)	JP (2)	CN (1)
Philippines (13)	IL (2)	
New Zealand (5)	PT (1)	
Portugal (3)	PH (1)	
Denmark (2)	MX (1)	
	GB (1)	
	DK (1)	

Immatics is a clinical-stage biopharmaceutical company based in Germany that is developing innovative immunotherapies for the treatment of cancer. The company's proprietary technology platform allows for the identification of targets on the surface of cancer cells that can be recognized by the immune system, and the development of T-cell receptor (TCR)-based immunotherapies that can selectively attack these cancer cells. Immatics is focused on developing immunotherapies for solid tumors, which account for the majority of cancer cases. The company's lead product candidate, IMA201, is a TCR-based immunotherapy for the treatment of solid tumors, and is currently in clinical trials.

Immatics also has a pipeline of other TCR-based therapies in development for various types of cancer (Immatics, 2023).

The Regents of the University of California is the governing board of the University of California system, which includes ten campuses, five medical centers, three affiliated national laboratories, and a statewide agriculture and natural resources program. The Regents are responsible for setting policy and overseeing the management of the university system. They also appoint the president of the University of California and other senior administrators (Regents, 2023).

In this dataset, the top five territories are: WO (2410 patents), US (2330), EP (1357), CA (1288) and AU (1190).

The most patent active inventors were Andrea Mahr, Toni Weinschenk, Oliver Schoor, Jens Fritsche Harpreet Singh and Lea Stevermann (52 patents, under Immatics Biotechnologies), Andrea Mahr, Lea Stevermann, Toni Weinschenk, Oliver Schoor and Harpreet Singh (27 patents, again under Immatics) and Oliver Schoor, Norbert Hilf, Toni Weinschenk, Claudia Tratwein, Steffen Walter and Harpreet Singh (14 patents, under Immatics).

In the Precision CAR T-cell therapy dataset out of the 155 results, 18 patents were filed by the applicant Leidos, Inc (WO 5, US 5, CA 4, AU 4). The following 3 applicants each have 6 patents: Janssen Biotech Inc (WO 1, US 1, IL 1, EP 1, CA 1, AU 1), Ohio State Innovation Foundation (WO 2, EP 1, CN 1, CA 1, AU 1) and The University of Washington Cancer Research Center (WO 2, US 2, CA 1, AU 1).

Leidos, Inc. is a US-based company that provides scientific, engineering, and information technology solutions to various industries, including defense, intelligence, homeland security, and health. The company's patent portfolio includes a wide range of technologies, including biotechnology, software, optics, and sensors, among others (Leidos, 2023).

The top territories of this dataset are WO (57), AU (30), US (27), CA (25) and EP (9 patents).

In summary, the answer to the KIQ1MG3 seems to be that in this field, the top three competitors with the most patents are Immatics Biotechnologies, Genentech, and The Regents of the University of California. Interestingly, the most active inventors were all associated with Immatics Biotechnologies. The territories where the highest number of patents were filed were WO, US, EP, CA and AU. In the Precision CAR T-cell therapy dataset, Leidos, Inc. was the most active applicant with 18 patents. The main territories for patent protection were WO, AU, US, CA, and EP.

In the Recall All dataset the results for top applicants were The United States of America as represented by the Department of Health and Human Services (183 patents), Novartis (150), The Board of Regents of the University of Texas (124), Dana-Farber Cancer Institute, Inc. (105), Medarex, Inc. (81) and Genentec (74). The table below depicts the top three territories for these top applicants.

United States Dep.	Novartis	University of Texas	Dana-Farber	Medarex	Genentec
US (109)	WO (31)	US (45)	WO (39)	US (18)	US (34)
WO (49)	AU (30)	WO (45)	US (32)	WO (18)	AU (12)
CA (14)	EP (22)	CA (17)	CA (14)	CA (15)	WO (110

The Department of Health and Human Services (HHS) is a cabinet-level department of the United States federal government. Its mission is to enhance and protect the health and well-being of all Americans by providing effective health and human services and fostering advances in medicine, public health, and social services. The HHS is responsible for a wide range of programs and initiatives related to healthcare, including healthcare research, disease prevention, healthcare delivery, Medicare and Medicaid services, public health emergency preparedness and response, and human services for vulnerable populations such as children, the elderly, and individuals with disabilities. The HHS has a significant impact on the health and well-being of Americans and plays a critical role in shaping the nation's healthcare policies (HHS, 2023).

The Board of Regents of the University of Texas is a governing body that oversees the University of Texas System, which comprises 14 educational and health institutions throughout Texas. As a research institution, the University of Texas is engaged in various research fields, including cancer, neuroscience, and energy (Utsystem, 2023).

Dana-Farber Cancer Institute, Inc. is a leading research and treatment center for cancer and related diseases. Based in Boston, Massachusetts, the Institute is affiliated with Harvard Medical School and is a member of the National Comprehensive Cancer Network (NCCN) (Dana-Farber, 2023).

Medarex, Inc. is a biotechnology company that specializes in the development of therapeutic antibodies to treat cancer, autoimmune diseases, and other medical conditions. The company has been involved in the development of several innovative drugs, including ipilimumab (Yervoy), which was the first FDA-approved immune checkpoint inhibitor for melanoma. Medarex is now a subsidiary of Bristol Myers Squibb (Linkedin Medarex, 2023).

When looking solely at the countries, the top five are: US 3240 patents, WO 2084 patents, EP 1489 patents, CA 1366 patents and AU 909 Patents. From this dataset, it can be concluded that the top three territories where applicants are seeking patent protection for the third model group of pharmaceuticals are US, WO and EP though it can be observed that the top applicants prefer Canadian patents over EP patents.

In the Recall CAR T-cell therapy dataset the results for top applicants were Novartis (28), Enlivex (26), The Regents of the University of California (25), The Trustees of the University of Pennsylvania (24) and Kite Pharma (21).

Enlivex Therapeutics is a biotechnology company focused on developing immunotherapy treatments for various immune-related diseases. The company's lead product candidate, Allocetra, is designed to modulate the immune system's cytokine storm and treat multiple indications, including bone marrow transplantation and sepsis (Enlivex, 2023).

The Trustees of the University of Pennsylvania is a private Ivy League research university in Philadelphia, Pennsylvania. The university is widely recognized as one of the world's most prestigious institutions of higher education and is known for its leadership in fields such as medicine, law, and business (UPENN, 2023).

Kite Pharma is a biopharmaceutical company focused on developing innovative cancer immunotherapies. The company's lead product candidate, Yescarta, is a CAR T-cell therapy approved by the FDA for the treatment of certain types of non-Hodgkin lymphoma. Kite Pharma was acquired by Gilead Sciences in 2017 (Kite, 2023).

The top territories of these top applicants are:

Novartis	Enlivex	Uni of California	Uni Pennsylvania	Kite Pharma
WO (6)	US (6)	WO (8)	WO (7)	WO (5)
US (3)	WO (4)	AU (8)	US (7)	US (4)
EP (3)	EP(4)	US (5)	CA (4)	EP (4)
CA (3)	CA (4)			
AU (3)	AU (4)			
IL (3)				

The top territories regardless of applicants are WO (233 patents), US (145), AU (111), CA (94) and EP (59).

In brief, the main competitors in the field vary depending on the dataset analyzed. In the Precision All dataset, Immatics Biotechnologies, Genentech, and The Regents of the University of California are the top three applicants with the most patents. In the Precision CAR T-cell therapy dataset, Leidos, Inc. was the most active applicant. In the Recall All dataset, the top applicants were The United States of America Department of Health and Human Services, Novartis, The Board of Regents of the University of Texas, Dana-Farber Cancer Institute, Inc., Medarex, Inc., and Genentec. In the Recall CAR T-cell therapy dataset, the top applicants were Novartis, Enlivex, The Regents of the University of California, The Trustees of the University of Pennsylvania, and Kite Pharma. The top territories for patent protection across all datasets were WO, US, AU, CA, and EP.

KIQ2MG3 (Key Intelligence Question 2 for Model Group 3): What are the current development trends within this model group?

For this particular model group, time is a crucial factor as the topic is highly current. Therefore, the two subprocesses of the previous model groups, which were divided based on publication year and the number of citations, have been combined into a single process. This approach ensures that the data's novelty and relevance are both given equal weight in the analysis.

WoS

TS=("cancer treatment" OR "targeted therapies" OR "molecular targets" OR "genetic targets" OR "monoclonal antibodies" OR "tyrosine kinase inhibitors" OR "immunotherapies" OR "checkpoint inhibitors" OR "cancer vaccines")

The search query shown above produced 344667 results. Refining by year (2023) reduced the results to 6037. 3 datasets were analyzed: 1) Most cited paper (Citations by highest first), 2) Most relevant papers and 3) Most recent (Date by newest first).

Based on the keywords provided by the authors of the 50 most cited articles, some current trends for Model Group 3 were:

- Biomimetic nanosystems for targeted drug delivery
- Immunotherapy, including the use of immune checkpoint inhibitors and immunogenic cell death
- Personalized treatment plans using machine learning and shared decision-making
- Development of new treatments for specific types of cancer, such as renal cell carcinoma and glioblastoma
- Combination therapies that use multiple treatment methods for improved efficacy
- Nanoparticle-based drug delivery systems
- Chemodynamic therapy, which uses metal-organic frameworks or Fenton catalysts to generate reactive oxygen species and induce cell death
- Use of extracellular vesicles as a drug delivery system
- Precision medicine, targeting specific molecular targets such as androgen receptors and COX-2
- Advances in single-cell screening and monoclonal antibodies
- Understanding the oncomicrobiome and its impact on treatment
- Investigating the potential of natural agents such as sanguinarine and bromelain for their chemo-preventive and cytotoxic effects on cancer cells.

Trends that came to light after evaluating the abstracts of the twenty most relevant articles:

- The use of immune checkpoint inhibitors (ICIs) and targeted therapies in cancer treatment.
- The role of tyrosine kinase inhibitors in treating different types of cancer, and the potential cardiovascular toxicities associated with these treatments.

- The potential of nano medicinal interventions and approaches to enhance the efficacy of tyrosine kinase inhibitors for cancer treatment through improved tumor-availability and reduced side effects.
- The impact of cancer treatments on bone metabolism and the development of sarcopenia.
- The need for more research into the mechanisms of cross-resistance and limitations of currently available cancer treatments.
- The development of new compounds as potential anticancer agents using molecular modeling strategies.
- The treatment of specific cancers, such as hepatocellular carcinoma, glioblastoma multiforme, and colorectal cancer, using targeted therapies and immunotherapies.
- The potential role of PCSK9 in atherosclerosis and cancer progression as a new pharmacological target.
- The use of therapeutic drug monitoring in cancer treatment.
- The treatment of multiple myeloma with new monoclonal antibodies and immunotherapies, with the goal of finding the best therapeutic combination among all available drugs.

From the search refined by newest results, the first twenty results were analyzed, and several recurring themes were detected (based on article title and keywords), including cancer treatment and therapies (particularly for lung, breast, and prostate cancer), immune-related research (such as immunotherapy and immune checkpoint inhibitors), development of monoclonal antibodies, and cost-effectiveness analysis of various treatments. Additionally, there are several titles that focus on specific aspects of cancer research, such as mRNA modification patterns, ultra-trace metal-protein interactions, and HPV31-specific monoclonal antibodies.

The analyses of the most cited articles, relevant abstracts, and newest search results suggest several recurring themes in current cancer research. These include the development of new treatments using immunotherapy, personalized medicine, and combination therapies, as well as advances in nanosystems and precision medicine. Additionally, there is a focus on understanding the impact of cancer treatments on other health issues, such as bone metabolism and cardiovascular toxicity. These trends highlight the importance of continued research and development in the field of oncology to improve cancer treatment outcomes and reduce the burden of the disease.

Overall, these abstracts suggest that cancer treatment is becoming more personalized, targeted, and multidisciplinary, with an increasing emphasis on immunotherapy and combination therapies.

Technology Roadmap example for MG3

Knowledge Asset Planning (KAP) is a roadmap that helps organizations identify and manage their intellectual property to gain a competitive advantage. This is especially important in the pharmaceutical industry, where intellectual property is critical for success. KAP involves assessing existing knowledge assets, identifying areas where new assets need

to be developed or acquired, and outlining a plan for managing and leveraging these assets to achieve strategic goals.

To conduct a KAP analysis for a pharmaceutical company, the following steps can be taken: first, identify the relevant knowledge assets, such as patents, scientific publications, clinical trial data, and regulatory filings. Next, assess the value of these assets based on their quality, relevance, and applicability to the organization's objectives. Then, develop a knowledge management strategy that outlines how these assets will be captured, stored, shared, and leveraged to support innovation and competitiveness. Metrics and targets should be established to measure the effectiveness of the strategy, and the strategy should be implemented and monitored to achieve desired outcomes.

To conduct a KAP analysis using data found on PatentScope, the start was by selecting a relevant applicant from the "Applicants" model group. Then, the search for patents filed by this applicant was done identify relevant knowledge assets. An assessment the value of these assets by analyzing their quality, relevance, and applicability to the organization's objectives can be done in the following step. The goal is then to develop a knowledge management strategy that outlines how these assets will be managed and leveraged. It is important also to establish metrics and targets to measure the effectiveness of the strategy and implement and monitor the strategy to achieve desired outcomes.

Overall, KAP is an essential tool for pharmaceutical companies to protect their intellectual property and gain a competitive edge. By conducting a KAP analysis, organizations can identify and manage their knowledge assets to support innovation and competitiveness.

Report of the applied process on an actual company:

This report outlines the process for creating a technology roadmap and a knowledge asset and property (KAP) roadmap for Leidos, Inc., a Fortune 500 company (Leidos, 2023) that offers technology and engineering solutions in various industries. For creating a technology roadmap, the process involved identifying goals, gathering information, analyzing the data, defining the roadmap, and then would also encompass communicating the roadmap, and executing the roadmap. For creating a KAP roadmap, the process involves identifying Leidos, Inc.'s strategic goals and objectives, assessing the company's current knowledge assets, identifying gaps and opportunities, developing a KAP roadmap.

To identify Leidos, Inc.'s strategic goals and objectives, the company's official website was examined. The list of potential strategic goals and objectives that Leidos, Inc. may have was compiled including expanding market share, increasing revenue, enhancing customer satisfaction, improving operational efficiency, developing new technologies, expanding globally, fostering a culture of innovation, and enhancing cybersecurity.

For assessing Leidos, Inc.'s current knowledge assets, a search was conducted on PatentScope to identify and consequentially analyze the company's existing knowledge and intellectual property. For the purpose of this study, the company’s stakeholders were not involved in the process, however, it is recommended to involve key stakeholders throughout the process to ensure buy-in and alignment with the company's goals and objectives.

Leidos, Inc. is a large company that provides technology, engineering, and science solutions and services to various industries, including defense, intelligence, civil, and health. The company possesses various knowledge assets, such as patents, trademarks, research and development activities, employee expertise, and data and analytics capabilities. Analyzing these assets would require a more detailed examination of their operations and intellectual property portfolio.

To gain insight into Leidos' patents, the search on PatentScope was conducted and yielded 189 results. In comparison with the Precision CAR T-cell therapy dataset, where Leidos, Inc. was the most active applicant with 18 patents (and the main territories were WO, AU, US, CA, and EP), the top five countries for their entire patent portfolio are US (132 out of the total 189 patents), AU (15), Wo (15), EP (11) and CA(8). It can be thus assumed that the company focus their patent efforts primarily within the United States of America. Their most recent patents include inventions related to sensor systems, deep neural network analysis, peptide conjugates, object detection architectures, and virus-based expression vectors. These inventions are aimed at a variety of therapeutic and technological purposes such as inhibiting the progression of diseases, enhancing response to vaccination, and improving imaging systems.

One notable invention is a horizontal acoustic vector sensor system that includes a gimbal assembly and multiple pairs of seismometers arranged orthogonally. The system also includes an omni-directional hydrophone integrated into the endcap. Another invention is an Activation Map Analysis (AMA) system that attaches to an existing deep neural network as an observer to provide additional information such as metrics for resilience, interpretability, and adversarial defense to the end-user. The AMA system is developed using deep k-nearest neighbor (DkNN) coupled with principal component analysis (PCA) for data dimensionality reduction or Hyperdimensional Computing (HDC) to encode activation map data of the host for data reduction. Leidos' knowledge assets enable the company to offer innovative solutions and services to various industries. Their patents demonstrate their focus on developing cutting-edge technology to address complex challenges in areas such as defense, intelligence, civil, and health.

Furthermore, Leidos is a company working on various research and development projects, some of which include AI and machine learning, cloud computing, cybersecurity, health and life sciences, autonomous systems, and energy and environment. To create the technology roadmap, the company should analyze its R&D pipeline, patent filings, and publications to identify key technologies, prioritize them based on potential impact on the business and market opportunities, and identify milestones and timelines for each technology, including development phases, regulatory approvals, commercialization, and market launch. Regularly reviewing and updating the technology roadmap is crucial to stay ahead of the competition and capitalize on emerging market opportunities. Leidos is currently researching key technologies such as activation map analysis systems, peptide conjugates, object detection architectures, PD-1 peptide inhibitors, peptides that bind to LAG3, and motion extended array synthesis technology. AI and ML, cybersecurity, and cloud computing are some of the prioritized key technologies based on their potential impact on Leidos' business and market opportunities.

Here are some potential milestones and timelines for the key technologies identified in the previous steps for Leidos:

1. Artificial Intelligence (AI) and Machine Learning (ML) Technology:

- Key Development Phases: Research and development, data collection and processing, algorithm testing and validation, product design and prototyping
- Commercialization: Integration of AI/ML technology into existing products and services, development of new AI-powered products and services
- Market Launch: Continuous integration and improvement of AI/ML technology, new product launches on an ongoing basis

2. Cybersecurity Technology:

- Key Development Phases: Research and development, vulnerability testing and assessment, product design and prototyping, penetration testing
- Commercialization: Integration of cybersecurity technology into existing products and services, development of new cybersecurity products and services
- Market Launch: Continuous improvement and integration of cybersecurity technology, new product launches on an ongoing basis

3. Health IT and Analytics Technology:

- Key Development Phases: Research and development, data collection and processing, algorithm testing and validation, product design and prototyping
- Regulatory Approvals: FDA approval for medical devices and software
- Commercialization: Integration of health IT and analytics technology into existing products and services, development of new health IT and analytics products and services
- Market Launch: Continuous improvement and integration of health IT and analytics technology, new product launches on an ongoing basis

The timelines and milestones for each technology will vary based on a variety of factors, including the complexity of the technology, the availability of resources, and the competitive landscape. These are just general estimates and Leidos may have its own specific timelines and milestones in place for each technology.

5.4 Conclusion to the Case Study

The pharmaceutical drug groups analyzed were selected for specific reasons. The medications used for thyroid gland disorders and disorders related to the function of thyroid hormones are the result of over a century of endocrine research. These drugs are highly effective in treating a range of distinct disorders with different mechanisms. The second group of drugs includes those used to control pain and inflammation, which patients can manage effectively themselves. The broad regulatory network involved in the perception of pain and inflammatory processes justifies the availability of these drugs for over-the-counter purchasing and for pharmaceutical research seeking new drugs for this purpose.

The third group of drugs includes anticancer pharmaceuticals, which represent the current state-of-the-art for treating genetic disorders leading to malignancies. Focused research has led to the discovery of effective interventions that can treat even genetically diverse disorders by targeting shared biological regulations that are impaired in different types of malignancies. As a subgroup of anticancer strategies, genetically modified T lymphocytes from patients are now being used to enhance their biological regulatory potential against cancer cells, regardless of the specific genetic disorder. It is expected that, similar to the first group of thyroid hormone-related disorder treatments, these contemporary cancer treatment strategies will lead to effective cures for cancer.

The Case Study showed the TI process on three model groups of drugs, showing various ways to obtain relevant information in order to answer the two Key Intelligence Questions that were proposed at the beginning of the TI lifecycle: finding the main competitors and locating where they are obtaining their patents. Determining the current trends based on the available data from established bibliographic databases used by researchers and scholars to find and access academic articles and research publications. In all the model groups, patent documents were examined to get a thorough understanding of the competitive environment for each sector.

Based on the results obtained from the analysis of the competitive environment, there are several informed decisions that can be made. For example, the identification of the top competitors in the field and the territories in which they seek patent protection can inform decisions about where to focus research and development efforts, and where to file for patent protection. Additionally, the analysis of the most patent-active inventors can help in making informed decisions about hiring and talent acquisition strategies. The identification of the top territories for patent protection can also help in making decisions about where to prioritize marketing and distribution efforts. Overall, the analysis of the competitive environment can provide valuable insights that can inform strategic decisions across various aspects of a business or organization.

In the first model group, the results of the Precision and Recall searches were downloaded and subsequently analyzed using Tableau, a data visualization and business intelligence software. The data was cleaned, organized, and analyzed with regard to the chosen KIQs. The top three territories where applicants are seeking patent protection for the first model group of pharmaceuticals were found to be WO, US, and CA. The World Intellectual Property Organization, which is an international organization headquartered in Geneva, Switzerland, has 193 member states and is responsible for the administration of international treaties dealing with patents, trademarks, and copyrights (WIPO, 2023). The fact that the top three territories where applicants are seeking patent protection for the first model group of pharmaceuticals are WO, US, and CA suggests that these countries are key markets for pharmaceutical companies seeking to protect their intellectual property. It also indicates that these countries are likely to have strong patent laws and regulations, which can provide a favorable environment for pharmaceutical innovation and investment. Additionally, it highlights the importance of international patent protection through organizations like WIPO, which can help companies protect their inventions in multiple countries simultaneously. Applications with the most patents were examined in both datasets to provide insight about the competitive environment.

The trends in hypothyroidism acquired through the analyses of non-patent literature appear to be improving diagnosis and treatment, understanding the relationship between hypothyroidism and other conditions, and exploring the impact of COVID-19 on thyroid function. Additionally, there is a focus on developing new technologies to aid in the diagnosis and treatment of thyroid disorders. The literature for this model group was obtained through Web of Science, analyzing publications from 2023 (KIQ2MG1a) and the top cited articles regardless of the publication year (KIQ2MG1b). A further analysis was conducted in PubMed. This analysis aimed to identify recent trends in research on the topic of hypothyroidism by examining the most recent publications available in the database and using the MeSH Keyword identifier 5819, which yielded 38,994 results. These results were sorted by best match, and the top 10 articles were selected for investigation. Based on the information contained in the abstracts of these publications, the analysis sought to identify common themes and areas of interest among researchers in this field. The identified trends in thyroid research concluded from the PubMed analyses include the use of levothyroxine in cancer treatment, exploring the relationships between thyroid hormones and other hormones or chemicals in the body, and the effects of iodine on thyroid health in pregnant women, as well as the use of thyroid hormones as potential biomarkers for cancer or the effects of various treatments on thyroid function, highlighting the diverse and multidisciplinary nature of the field.

The second model group analyzed in this study consisted of non-steroidal anti-inflammatory drugs (NSAIDs), which are commonly used to reduce pain and inflammation. The process for analyzing this model group was similar to the first, involving defining the scope, creating keywords, and collecting and cleaning data. The first Key Intelligence Question (KIQ1MG2) for this group focused on identifying the main competitors and their patent protection in different territories. Two Precision datasets were analyzed along with one Recall dataset. Top applicants and top inventors were investigated with regards to their patent locations. The top three countries for patent protection across all three datasets were the same: US, WO, and EP.

The second Key Intelligence Question was approached similarly in the second model group as in the first, but instead of PubMed, Scopus was utilized. The scientific literature search was conducted to identify current development trends in nonsteroidal anti-inflammatory drugs (NSAIDs) and related topics. Within the publications from 2023, some current trends related to NSAIDs included molecular modeling, toxicity and side effects, novel drug delivery systems, biodegradation, multi-target drugs, natural products, designing NSAIDs, targeted drug delivery, NSAIDs and pain management, NSAIDs and inflammation, and NSAIDs and diseases. The trends suggest a focus on designing and developing new NSAIDs, targeting drug delivery systems, and exploring natural products as potential adjuvants for pain management. The search in Scopus generated 628015 results, and the most prolific authors, institutions, and funding sponsors were identified. Several filtering techniques were employed to refine the search results, including the exclusion of opioid-related articles and the application of a timeframe filter to focus on the most current and relevant literature in the field.

An additional patent analysis was conducted to identify recent developments in this field of pharmaceuticals. The added analysis involved examining the abstracts of the 10

most recently published patents obtained from PatentScope concerning the subject field of the model group. The additional patent analysis involved examining the abstracts of the 10 most recently published patents obtained from PatentScope. The analysis revealed several specific developments in drug discovery and treatment, including novel drug delivery systems, potential treatments for neurodegenerative and neuropsychiatric disorders, pain management formulations, treatments for viral infections such as SARS-CoV-2, and the use of ammonia oxidizing microorganisms for treating urogenital and inflammatory disorders. However, there were no discernible overarching trends in the field of pharmaceuticals or medicine as a whole.

The third and final model group conferred targeted therapies and immunotherapies as groups of anticancer drugs designed to target specific molecules or pathways involved in cancer cell growth and development. Examples of targeted therapies include monoclonal antibodies, tyrosine kinase inhibitors, and immunotherapies, such as checkpoint inhibitors and cancer vaccines. CAR T-cell therapy is a type of immunotherapy that involves genetically engineering a patient's T cells to produce special receptors that recognize and attack cancer cells. The TI process was repeated for Model Group 3, which involved conducting a search using specific keywords and queries on the PatentScope database to collect relevant data on cancer treatment patents. Two Precision and two Recall datasets were obtained and observed. In the Precision All dataset, Immatics Biotechnologies, Genentech, and The Regents of the University of California are the top three applicants with the most patents, while Leidos, Inc. was the most active applicant in the Precision CAR T-cell therapy dataset. The top applicants in the Recall All dataset were The United States of America Department of Health and Human Services, Novartis, The Board of Regents of the University of Texas, Dana-Farber Cancer Institute, Inc., Medarex, Inc., and Genentec. In the Recall CAR T-cell therapy dataset, the top applicants were Novartis, Enlivex, The Regents of the University of California, The Trustees of the University of Pennsylvania, and Kite Pharma. Across all datasets, the top territories for patent protection were WO, US, AU, CA, and EP.

The second Key Intelligence Question aimed to identify the current development trends within Model Group 3 by analyzing refined search results obtained from three separate searching strategies conducted on the Web of Science database, namely, the most cited, most relevant, and newest publications. The analysis revealed that current research trends within the model group include the exploration of biomimetic nanosystems for targeted drug delivery, the use of immunotherapy, the development of personalized treatment plans using machine learning, and the investigation of new treatments for specific types of cancer. Other important areas of research include combination therapies, nanoparticle-based drug delivery systems, and chemodynamic therapy. Precision medicine, monoclonal antibodies, and understanding the oncomicrobiome have also emerged as significant research areas. Furthermore, researchers are focusing on gaining a deeper understanding of the impact of cancer treatments on other health issues, such as bone metabolism and cardiovascular toxicity. Collectively, these findings suggest that cancer treatment is becoming more personalized, targeted, and multidisciplinary, with an increasing emphasis on the use of immunotherapy and combination therapies.

Additionally, the process for conducting technology roadmap analysis was outlined, which included identifying relevant knowledge assets, assessing their value, developing a knowledge management strategy, and the recommendation of implementing and monitoring the strategy. An example of the application of creating a technology roadmap was conducted for the company Leidos, Inc., a Fortune 500 company that provides technology and engineering solutions in various industries. The process involved identifying goals, gathering information, analyzing data, defining the roadmap, communicating the roadmap, and executing the roadmap. A search on PatentScope was conducted to identify Leidos, Inc.'s existing patents. Leidos, Inc. is a company focused on developing cutting-edge technology in various fields, including defense, intelligence, civil, and health. Their patent portfolio demonstrates a focus on innovation in multiple areas such as sensor systems, deep neural network analysis, peptide conjugates, object detection architectures, and virus-based expression vectors, among others. Leidos' R&D pipeline includes AI and machine learning, cloud computing, cybersecurity, health and life sciences, autonomous systems, and energy and environment. The company should analyze its R&D pipeline, patent filings, and publications to identify key technologies and prioritize them based on potential impact on the business and market opportunities. Key technologies include AI and ML, cybersecurity, and health IT and analytics.

Overall, the results suggest that the proposed procedure can effectively analyze the external environment of pharmaceutical companies and organizations using open data and identify trends in selected drug sectors. Based on the results obtained from the analysis of the competitive environment, there are several informed decisions that can be made. For example, the identification of the top competitors in the field and the territories in which they seek patent protection can inform decisions about where to focus research and development efforts, and where to file for patent protection. Additionally, the analysis of the most patent-active inventors can help in making informed decisions about hiring and talent acquisition strategies. The identification of the top territories for patent protection can also help in making decisions about where to prioritize marketing and distribution efforts. Hence, the analysis of the competitive environment can provide valuable insights that can inform strategic decisions across various aspects of a business or organization.

6 Conclusion

This chapter is a summary of the key findings, discussion of the implications of the research, and offers recommendations for future research or action. This Master Thesis focused on technology intelligence processes for the healthcare sector, with an emphasis on the analysis of patent documents and non-patent literature. The research was divided into three model groups of pharmaceutical drugs: medications for reduced function thyroid gland disorders, non-steroidal anti-inflammatory drugs and analgesics, and anticancer drugs. The work was divided into four parts: the first part describing the TI life cycle and its potential applications in the pharmaceutical industry, the second part providing a comprehensive analysis of patent documents, including a detailed explanation of the application process along its Process map diagram depiction, the third part presenting the specific TI inputs based on defined key questions and information sources and then demonstrates the technology intelligence process on the three model groups, and the fourth part synthesizing the results with a final discussion. The main aim of this work, creating a procedure for the TI process, was carried out and then showcased on the three model groups of drugs in the Case Study of the work.

The primary objective was to propose a procedure for utilizing patent and non-patent information entities in the area of Technology Intelligence for analyzing the external environment of pharmaceutical companies and organizations, as well as identifying trends in selected drug sectors. To attain the objective, a set of sub-goals, each with its own research questions, was selected:

The first subgoal and research question was focused on identifying and classifying relevant patent and non-patent information entities for the field of Technology Intelligence in the pharmaceutical industry while demonstrating a Technology intelligence procedure within the three model groups. This was successfully proven in the Case Study of this work.

The second subgoal aimed to develop a procedure for the collection and analysis of information entities using open source data and contained the research question seeking to understand the effective use of open data sources in collecting and analyzing information entities for technology intelligence in the pharmaceutical industry. The developed procedure was able to identify relevant information entities from open data sources and analyze them to provide meaningful insights into technology trends in the pharmaceutical industry.

Based on the analysis conducted in the case study, it can be concluded that the third subgoal, which was to identify trends in the selected drug sectors using the collected and analyzed data, was successfully accomplished. The data collected through various sources was analyzed and trends were identified in each of three model groups. These trends provided valuable insights into the current and future state of the industry, which could be leveraged to make informed decisions about investments, research, and development. Overall, the achievement of this subgoal has contributed to a deeper understanding of the drug sector and has paved the way for the attainment of the broader research objectives.

The final subgoal was to evaluate the effectiveness of the proposed procedure for technology intelligence analysis in the pharmaceutical industry. The Research question "How effective is the proposed procedure for technology intelligence analysis in the pharmaceutical industry as evaluated through the identification of trends in selected drug sectors?" was meant to show to what extent is the suggested method for technology intelligence analysis in the pharmaceutical sector successful in identifying trends within specific drug sectors, as determined through the analysis of the results obtained. Based on the results obtained in the case study using PatentScope, it is evident that the process for evaluating the competitive environment was effective. The data from PatentScope revealed the top applicants with the most patents, active inventors, and the territories in which they sought patent protection. The information provided by PatentScope was crucial in understanding the competitive landscape within this industry. By evaluating the patent activities of the top applicants, it was possible to identify the main competitors in the field and their areas of focus. This information can be used to develop strategies to stay ahead of the competition. The use of PatentScope proved to be a valuable tool in evaluating the competitive environment and provided insightful data to make informed decisions.

Overall, the Case Study successfully demonstrated the TI process within the pharmaceutical industry and provided valuable insights into the competitive landscape and current trends for each model drug group. The findings can inform strategic decisions for businesses and organizations in the industry, and future research can further improve the TI process through open-source data and other innovative methods. The goals defined in the introduction were fulfilled, confirming that TI processes are crucial within the pharmaceutical industry.

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