Patent Map for an Innovative Surgical Stapler

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Patent Map for an Innovative Surgical Stapler

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Abstract

The goal of this project was to develop a patent map for surgical staplers in partnership with sponsor Summed Taiwan, a venture capital company based in Taiwan. The patent map helped identify technological voids and areas of potential infringement in the patent landscape prior to the development of a novel surgical stapler technology. At the conclusion of the project, the team presented a Technology-Function table (patent map) and list of patent briefs as deliverables. The team developed several design recommendations for the sponsor utilizing these deliverables. The social implications of an innovative surgical stapler include improving ease of operation for surgeons, the quality of life of their patients, and Taiwan's position in the medical device market.

Executive Summary

Motivation

In its endeavor to become a major player in the medical device industry, Taiwan is an appealing market for investment. With significant and continuous progress in recent years, Taiwan is realizing its potential as a global innovation and mass production base for medical devices. Pushed by trade sanctions and growing global competition, Taiwan's Intellectual Property (IP) market has developed a modern commercial approach to patent security (Park & Yoon, 2014). The underlying legal frameworks behind IP protection are critical for both the capital and technology markets to evolve at a rapid but stable pace. At present, medical devices remain at the forefront of Taiwan's target markets in the biomedical industry. The medical device market in Taiwan encompasses a diverse variety of equipment and goods used in patient diagnosis and treatment (Wang, 2021). In the future years, the sector is predicted to expand, owing to Taiwan's growing population and increased demand for healthcare products and services (International Trade Administration, 2021).

The medical community widely recognizes that the current models of surgical staplers and other endoscopic devices have an array of associated risks, including postoperative bleeding, sepsis, and even possible death. Surgical staplers are a key tool used to cut, seal, connect, or remove tissue during various types of internal surgeries including resection, transection, and anastomoses (U.S. Food and Drug Administration, 2021).

Figure 0.1. Surgical Stapler sold by Johnson & Johnson Ethicon. (Johnson & Johnson, 2022)

Our sponsor, Summed Taiwan, is a venture capital (VC) company dedicated to identifying unmet needs in healthcare and medicine, fostering the development of new medical technologies in Taiwan, and bringing them to market (Summed Taiwan, 2022). Summed Taiwan invests in startups innovating new medical devices and currently aims to initiate research on the patent landscape for surgical staplers. Operative risks and mechanical feature deficiencies found in surgical staplers have motivated Summed Taiwan to identify an opportunity for developing a competitive and innovative design to improve stapler functionality (S. Yeh, personal communication, 2022).

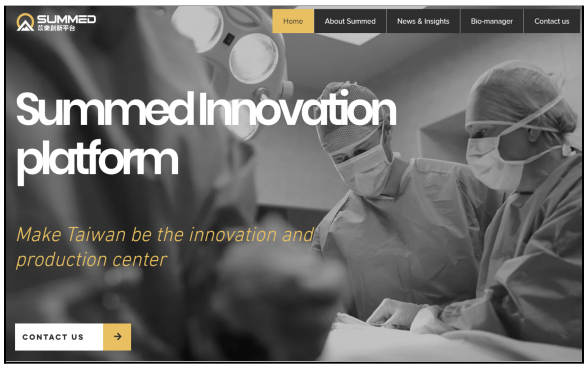

Figure 0.2. Screenshot from Summed Taiwan's Website. (Summed Taiwan, 2022)

The goal of this project was to assist Summed Taiwan with its feasibility study and lay the groundwork for Freedom to Operate (FTO) patent analysis for an innovative surgical stapler end effector (cartridge) design. An FTO analysis concerns the use or commercialization of a product or process without causing infringement upon the IP rights of others (Thomson Reuters, 2022). For the purpose of doing business in Taiwan, foreign stakeholders must understand Taiwan's patent regulations, as well as other types of IP protection available. For this project, Summed Taiwan requested two main deliverables from the team: a patent map (Technology-Function Table) and a list of patent briefs related to surgical stapler cartridges. In addition, Summed Taiwan requested that the team identify the technological voids in the patent map and present several design recommendations that address these gaps.

Approach

The team utilized a combination of archival research and interviews to identify the legal challenges and social implications of designing a novel surgical stapler, as well as inform the patent map and brief list content. The team defined four primary objectives to guide the development of the project deliverables:

1. Identified stapler functions, key features, and technical terms in patents to create an initial Technology-Function (T-F) table.
2. Applied Boolean grammar to filter and acquire data from patent databases to create patent briefs and an improved T-F table.
3. Conducted interviews with medical device and legal professionals to inform the team's understanding of the surgical stapler market and legal principles.
4. Utilized T-F table (patent map) to identify opportunities in the patent landscape for improvements.

To enhance the project background and major findings, the team interviewed seven individuals via Zoom: two biomedical-affiliated professors, two legal experts, and three medical device experts. Furthermore, the team conducted archival research within patent databases to extract the necessary information for the list of patent briefs and T-F table.

Results

Social Implications of Surgical Stapler Innovation in Taiwan

The team gained knowledge on surgical stapler innovation in Taiwan and its relevance beyond monetary return using both medical and economic perspectives. In Taiwan, Johnson & Johnson's Ethicon and Medtronic's Covidien have a duopoly on the surgical stapler market. Frank Chen, current biomanager of Summed Taiwan, assessed the market as nearly 50-50 between these two companies (F. Chen, personal communication, 2022).

The global medical device industry anticipates a new era of enhanced opportunity to provide more efficient and comprehensive goods to the general public and healthcare professionals. While Taiwan has a long history as a pioneer in the electronics industry, its influence in the medical device industry is still in its early stages. With only two significant rivals in the field of surgical stapler development, the

industry is ripe for growth. Summed Taiwan aspires to become a key participant in the surgical stapler business, joining the present group of dominant international corporations (F. Chen, personal communication, 2022).

Technical Issues with Surgical Staplers

To identify important mechanical and operating challenges motivating Summed Taiwan's creation of a new surgical stapler, the team questioned promoters and operators of current surgical staplers on the market. The team's literature review on FDA surgical stapler recalls and reports on the hazards of staplers was reinforced by these interviews, which gave a first-hand perspective.

In an interview with Taiwanese general surgeon Dr. Wei-Hsun Lu, he identified three issues regarding stapler design based on his experience operating surgical staplers (W.-H. Lu, personal communication, 2022):

1. Slippage between the stapler gripping surface and tissue may lead to malformation of the staple
2. Limitations on the bending angle of the stapler make it difficult for surgeons to accurately apply staples
3. The stapler's large size makes it challenging to maneuver in the limited space available during surgery

Patent Search & Visualization Tools

To accomplish the team's objective of applying Boolean grammar to filter and acquire data from patent databases, the team compared various patent databases, search strategies, and visualization tools. The team utilized three patent databases for archival research: Google Patents, GPSS, and The Lens. The team utilized GPSS and Google Patents in parallel during the initial stages of developing the Boolean search strategy for narrowing the search results to a reasonable number of patents: under 500 patents. Ultimately, the team chose to use The Lens as the final patent database from which the team exported patent information for the list of patent briefs. After condensing the patent abstracts down, removing duplicates, and organizing the list to include key information such as legal status and expiration date, the list contained a total of 60 patents.

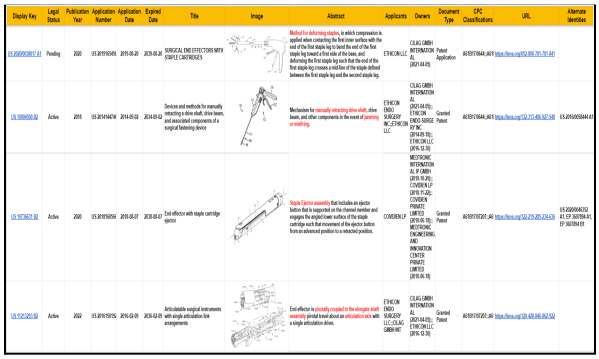

Figure 0.3. Section of final patent brief list.

T-F Table & Technological Voids

The main deliverable for this project was completing a functional T-F table and respective patent briefs for Summed Taiwan to utilize in FTO analysis of the surgical stapler market.

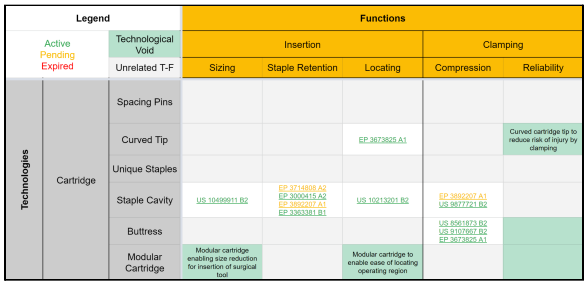

Figure 0.4. Sectional view of the T-F table focusing on several technological voids for the surgical stapler cartridge.

With the T-F table the team was able to determine the practicality of patent

mapping for uncovering these technological voids. By identifying these voids, the table fulfills the preliminary steps in an FTO assessment and is a valuable resource for Summed Taiwan to reference before seeking the aid of legal professionals.

In addition to the technological voids identified in the T-F table patent map, the team found additional several areas for improvement through the interviews conducted with medical device professionals. Dr. Lu commented on common complaints with current surgical staplers used in hospitals and provided three suggestions for improvement: improve gripping surface for holding tissue, increase bending angle of the end effector, and reduce the overall stapler size (W.-H. Lu, personal communication, 2022).

Conclusion & Recommendations

The team combined feedback from interviews with medical device experts and the technological voids identified in the T-F table to generate three cartridge-focused design recommendations for Summed Taiwan.

1. Curved cartridge tip to reduce risk of injury during clamping of tissue
2. Modular cartridge to assist with minimizing overall size and improving maneuverability of the device during insertion and location of the tissue region
3. Modified or improved distance between staples to improve staple accuracy and prevent leakage

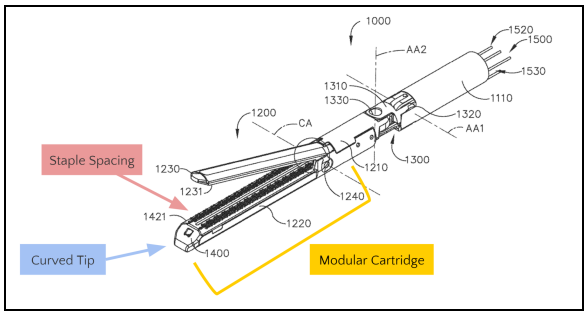

Figure 0.5. Annotated drawing of surgical stapler cartridge design recommendations with base drawing from US20210186498A1. (Chad P. Boudreaux et al., 2021)

The team faced various challenges and encountered several limitations throughout this project that may be circumnavigated in future projects. The project's short seven-week timeline made creating the appropriate search strategy and the full set of deliverables a challenge for the team. Nevertheless, the team recorded thorough documentation of the patent databases, visualization tools, and search strategy development process, all of which will be a key resource for accelerating patent archival research in future projects.

Executive Summary References

Chad P. Boudreaux, Frederick E. Shelton, IV, Chester O. Baxter, III, Michael J. Stokes, & Jason L. Harris. (2021). *Surgical Instrument Comprising a Rapid Closure Mechanism* (Patent No. US20210186498A1).

Chen, F. (2022). *Interview* [Personal communication].

International Trade Administration. (2021). *Medical Devices*. Taiwan - Country Commercial Guide. https://www.trade.gov/country-commercial-guides/taiwan-medical-devices

Johnson & Johnson. (2022). *Home | J&J MedTech*. https://www.jnjmedicaldevices.com/en-US/

Lu, W.-H. (2022). *Interview* [Personal communication].

Park, I., & Yoon, B. (2014). A semantic analysis approach for identifying patent infringement based on a product–patent map. *Technology Analysis & Strategic Management*, *26*(8), 855–874. https://doi.org/10.1080/09537325.2014.909926

Summed Taiwan. (2022). *About Summed*. https://www.summedtw.com/%E9%97%9C%E6%96%BC%E8%8B%A1%E6%A8%82?lang=en

Thomson Reuters. (2022). *Freedom to Operate (FTO)*. Thomson Reuters Practical Law Glossary. https://uk.practicallaw.thomsonreuters.com/2-511-4689

Wang, D. (2021). *Biomedical industry receives major priority focus in Taiwan*. Nextrend Asia. https://nextrendsasia.org/biomedical-industry-receives-major-priority-focus-in-taiwan/

Yeh, S. (2022). *Interview* [Personal communication].

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1.0 Introduction

The medical community widely recognizes that surgical staplers and other endoscopic devices have an array of associated risks, including postoperative bleeding, sepsis, and even possible death. During a lung-wedge resection of an 80-year-old lung cancer patient, doctors found a “sharp protruding edge created by multiple firings of the endostapler used in the procedure. Subsequent lung expansion would have promoted a direct contact between the edge and parietal pleura resulting in delayed bleeding” (Yamano et al., 2020). Between 2011 and 2018, the U.S. Food and Drug Administration (FDA) received over 41,000 individual medical device reports exceeding 32,000 malfunctions, over 9,000 severe injuries, and 366 deaths due to complications with internal surgical staplers and staples (U.S. Food and Drug Administration, 2019). The FDA sent several letters in 2019 and 2021 to inform medical providers of these issues and ended up classifying surgical staplers as a Class II (special controls) medical device, acting on these major threats to the quality of life of thousands (U.S. Food and Drug Administration, 2021).

Our sponsor, Summed Taiwan, is a venture capital (VC) company dedicated to identifying unmet needs in healthcare and medicine, fostering development of new medical technologies in Taiwan, and bringing them to market. Operative risks and mechanical feature deficiencies found in surgical staplers motivated Summed Taiwan to identify an opportunity for developing a competitive and innovative design to improve stapler functionality. Summed Taiwan invests in startups innovating new medical devices and currently aims to initiate research on the patent landscape for surgical staplers.

Patent regulations shape the technological arena for startups, making it a complex area to navigate as they seek to introduce new and improved medical technologies. The goal of this project was to develop a patent map that helps identify technological gaps in the surgical stapler market as part of a preliminary Freedom to Operate (FTO) analysis, to help navigate the complex patent arena. The team determined four objectives to accomplish this goal:

1. Identify stapler functions, key features, and technical terms in patents to create an initial Technology-Function (T-F) table.
2. Apply Boolean grammar to filter and acquire data from patent databases to create patent briefs and an improved T-F table.
3. Conduct interviews with medical device and legal professionals to inform the team's understanding of the surgical stapler market and legal principles.
4. Utilize T-F table (patent map) to identify opportunities in the patent landscape for improvements.

The team utilized archival research in patent databases to develop and refine the project deliverables, which included a final T-F table and a list of patent briefs. Interviews with medical device and legal professionals helped inform the team about the challenges of conducting a FTO analysis, useful patent search tools, current issues with staplers, and the significance of surgical stapler innovation in Taiwan.

2.0 Literature Review

A patent gives inventors the right to prevent others from creating, using, selling, or trading a technology. In other words, governments provide the assignee with an effective "monopoly" over the specific technology for the duration of the patent—usually 15 to 20 years from the date of filing (T. Keiller, personal communication, 2022). Since patents provide exclusive rights to inventions, they have an important role in the research and development (R&D) of new medical technologies. Researchers and analysts have developed patent mapping techniques to determine new areas of research that avoid regions of infringement.

Companies and applicants build a patent portfolio based on strategic business or development goals. As there is an increase in total patents in a given area, the value of a strong intellectual property (IP) portfolio grows. Patent maps have become popular for identifying a company's technical constraints or market prospects (Abbas et al., 2014). This chapter will investigate the extent to which patent mapping aids in identifying limitations and opportunities during the development of new medical devices. Illustrating the potential for surgical stapler development in Taiwan involves the following: visualizing technological voids in the market using a patent map, understanding IP regulations, and examining the effect of guidelines on patent applications and commercialization.

2.1 Surgical Staplers

Internal surgeries to connect tissue during resection, transection, and anastomoses can often benefit from the utilization of surgical staplers. Surgeons may use surgical staplers when cutting, sealing, connecting, or removing sections of organs and tissues (U.S. Food and Drug

Administration, 2021). A typical surgical stapler, as pictured in Figure 2.1, consists of three main portions: the proximal end, the elongated shaft, and the distal end. The proximal end (labeled 20) comprises the handle and trigger assembly of the stapler and provides feedback while allowing the surgeon to sever tissue and fire staples. The elongated shaft (labeled 32) provides spacing between the proximal and distal ends, thus allowing for the insertion of the distal end into the patient while keeping the proximal end at a safe distance. The distal end, or end effector, (broken out in the second sub-figure) houses a clamping apparatus, a knife blade for severing tissue, the staples, and a staple firing mechanism to seal the cut tissue (Frederick E. Shelton, IV, et al., 2006).

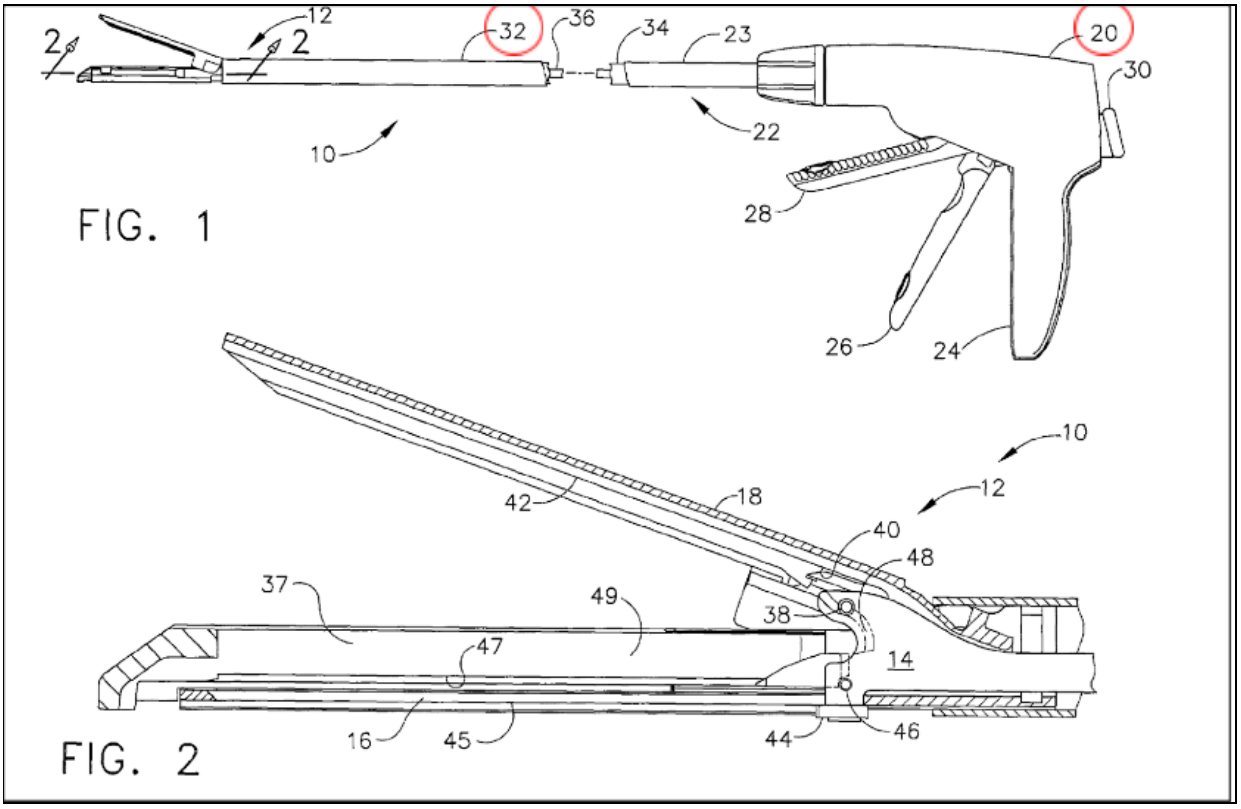


Figure 2.1. Surgical stapler design. (Frederick E. Shelton, IV, et al., 2006)

The first surgical stapler dates to 1908, when Hungarian surgeon Hümér Hültl and Hungarian surgical device designer Victor Fischer developed the first internal stapler design concept. Surgical staplers went through various stages of revision, gradually transforming to the initial outline of today's linear-style surgical staplers as early as 1934. The 1960s and 1970s exhibited major growth in the surgical stapler market as Johnson & Johnson (J&J) Ethicon and the United States Surgical Corporation (now known as Medtronic Covidien) began developing modern staplers (Gaidry et al., 2019).

Surgical staplers have become a preferred tool for surgeons, reducing both surgery time and complexity. Traditional hand-severing and suturing in the operating room could add up to an hour onto surgery, not only increasing the time spent in the operating room but also the risk of an injury-causing accident. In contrast to these manual methods for severing and re-sealing tissue, operating a surgical stapler takes a much smaller amount of time—on the order of minutes (F. Chen, personal communication, 2022). The reduction in time helps minimize risk of human error and provides convenience for already time-constrained surgeons (W.-H. Lu, personal communication, 2022).

Despite the numerous benefits of surgical staplers, in 2019 and 2021 the FDA distributed several letters to healthcare providers describing new recommendations and actions regarding the device’s safety profile after receiving numerous reports of malfunctions, injuries, and deaths related to internal staplers (U.S. Food and Drug Administration, 2021). Common issues identified in these reports included the malformation, misfiring, difficulty or failure to fire, and misapplication of staples.

In April 2019, the FDA conducted a Class I recall—the most severe type—of J&J Ethicon's endo-surgical staplers, identifying defects causing serious consequences and possible death. Not long after, in October 2019, the FDA announced another Class I recall for Ethicon's Echelon Flex Endopath Staplers (U.S. Food and Drug Administration, 2022). According to the FDA medical device recall report posted on October 29, 2019:

> "[t]he staplers may contain an out of specification anvil component within the jaw of the device. This condition may lead to malformed staples, which can compromise staple line integrity. If the staple line is compromised, there is a potential risk of prolonged surgery, postoperative anastomotic leak, hemorrhage, hemorrhagic shock, additional surgical intervention, or death" (U.S. Food and Drug Administration, 2019).

After the second recall, the FDA issued "a final order reclassifying surgical staplers for internal use from Class I (general controls) to Class II (special controls)" medical devices (U.S. Food and Drug Administration, 2021). The new classification required surgical staplers to undergo more stringent premarket reviews, regulations, and labeling recommendations to inform surgeons of specific instructions and associated risks. Because new models have unique interaction characteristics with the organs or tissue, trained surgeons can optimally utilize the device; while those who are unaware of the limitations during operation risk a "'knowledge gap' that is potentially dangerous" (Chekan & Whelan, 2014).

2.2 Patent Maps

This project examined the use of patent mapping to represent all technological categories of a surgical stapler prior to its new development. A patent map is a graphical or tabular model of displaying patent data, and can play an important role in identifying opportunities during the R&D of medical devices. There are various methods of patent mapping, with bibliographic or

citation-based patent maps historically popular in the field. Recently, the most widely adopted approach has been keyword-based patent mapping (Lee et al., 2009).

The history of patent mapping and how it has transformed into today's tools have been essential in identifying the characteristics of a successful patent map. When examining the differences between types of patent maps, there are several important characteristics: the number of patents and citations included within the database, the ability to effectively measure similarity between patents, and the user-friendliness of visualization formats (S. Yeh, personal communication, 2022). A high-quality patent map satisfies these points, whereas an unsatisfactory patent map has limited capabilities in any of these areas. Several academic researchers proposed a U.S. Patent and Trademark Office (USPTO) patent map interface developed from a database that identifies citation similarities between patents (Leydesdorff et al., 2014). The map utilized animated base maps, shown in Figure 2.2, and overlays that employ the World Intellectual Property Organization (WIPO) International Patent Classification (IPC) and Cooperative Patent Classification (CPC) codes to categorize and gather data on patents. These classification codes are used to identify the contents of a patent in a uniform matter; CPC is an extension of the IPC and is jointly directed by the EPO and the USPTO.

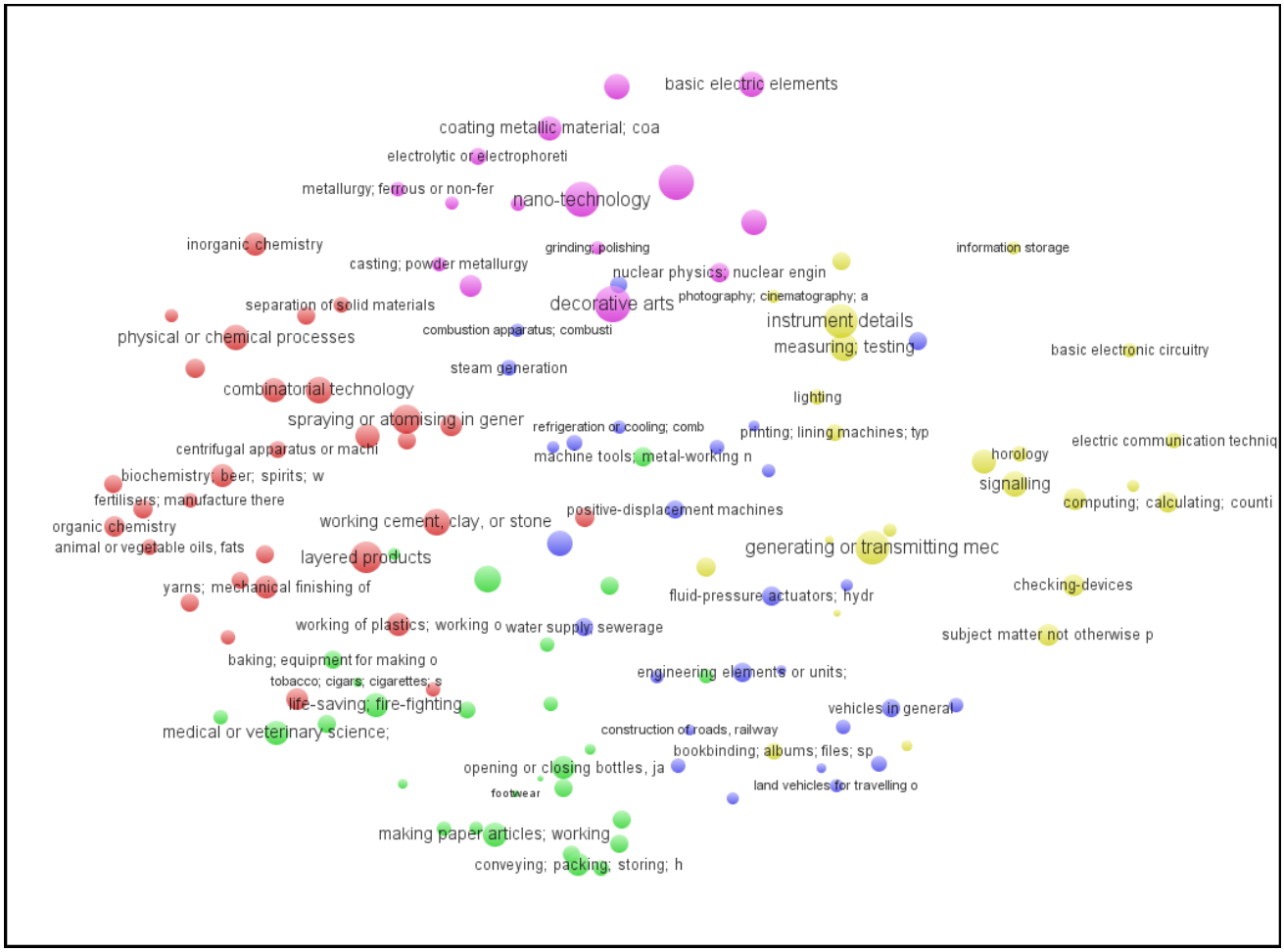


Figure 2.2. Base map showing IPC categories at the 3-digit level. (Leydesdorff et al., 2014)

IPC and CPC code classifications are strings assigned to a patent that denote the field of invention to varying levels of precision. For example, a four digit IPC classification relevant to this project is A61B. The first digit is the highest level of classification. The “A” denotes that the invention disclosed in the patent relates to human necessities. The next two digits “61” denote that the invention is specific to hygiene in medical or veterinary science. Finally, adding “B” as the fourth digit indicates that the patent’s invention is relevant to diagnosis, surgery, or identification (Espacenet, 2019). The classification can be more specific, as seen later with

classifications of over 10 digits in length. However, for the purposes of this example, four digits was sufficient. A visual breakdown of this example can be seen in Figure 2.3.

Symbol	Classification and description
A	HUMAN NECESSITIES
	HEALTH; AMUSEMENT
A61	MEDICAL OR VETERINARY SCIENCE; HYGIENE
A61B	DIAGNOSIS; SURGERY; IDENTIFICATION (analysing biological material G01N, e.g. G01N 33/48; obtaining records using waves other than optical waves, in general G03B 42/00)

Figure 2.3. IPC breakdown for A61B. (Espacenet, 2019)

Research has shown that using IPC and CPC codes to identify specific patents is a common technique used in patent maps due to the universal nature of the patent coding system. Employing the coding technique when patent mapping is important to illustrate technological gaps, portfolio diversity, and the development of a particular technology over time (Leydesdorff et al., 2014).

Keyword-based patent maps provide a visualization of the IP infringement and technological gaps between products and patents. A journal article by researchers at Ajou University, Dongguk University, and Seoul National University detailed the principal components of a keyword-based patent map methodology, shown in Figure 2.4, including how to convert patents into identifiable data and keywords, organize the data into a two-dimensional map, and how to evaluate gaps in the map (Lee et al., 2009). The process below consists of four main stages of the patent mapping process. First, one uses a search database to collect patents. The next step is to store patents, remove duplicated patents, and prepare them for analysis. Next is the text mining phase of the process, extracting the most important keywords from each stored patent. Finally, these keywords help to populate the desired patent map, such as a tabular patent

map, allowing for a better visualization of the patent arena and technological voids in a specific field.

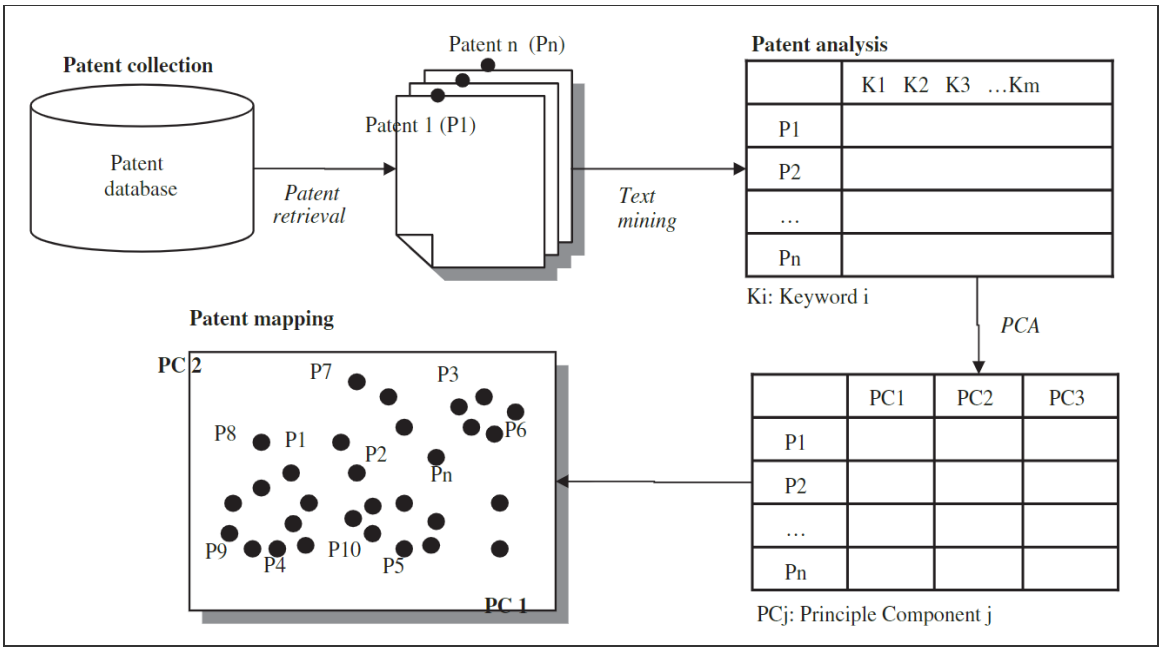


Figure 2.4. Patent map development process. (Lee et al., 2009)

However, there are limitations to keyword-based text mining, as it may not fully capture the multifaceted relationships between critical parts of a patent or product, risking infringement. While analyzing these relationships through text mining is a powerful tool, it can oversimplify the similarity between searchable objects defined by complicated sets of terms to a single score. Important information may be lost due to simplification and obfuscation during text mining. Thus, researchers outlined a new methodology of using subject-action-object semantics (sentence structure with subject first, verb second, and object third) to measure technological similarities and extract critical information from large unstructured documents (Park & Yoon, 2014). It is projected that these developments in computer technology boost text mining's efficiency and accuracy, enhancing its benefits. An important capability for patent maps is to

improve the organization and identification of potential areas of infringement, as this quality helps companies determine how to frame a patent infringement litigation and which patents to utilize as evidence.

2.3 Visualization of Technological Voids

Patent mapping plays a key role in the early stages of R&D for investors looking to visualize current technological voids in the market (Yoon et al., 2013). The team interviewed Professor Yihao Zheng from the department of Mechanical Engineering at WPI, whose research focuses on medical device design and innovation. In the interview, Professor Zheng expressed that for a product to have patentability, it must be novel, non-obvious, and have unique utility. Furthermore, he shared that novelty is defined as something that is not present in the previous "art", with patent maps being able to identify the novelty of the technology (Y. Zheng, personal communication, 2022).

In addition to patentability, FTO is another important critical component of patent security that defines an invention's commercial viability. A patent does not necessarily give an inventor the complete freedom to create, sell, use, or import the technology. A new device in development can reference existing patents that describe other aspects of the new device, which is the true meaning of having FTO (Yock et al., 2015). An FTO search is aimed at locating claims of currently pending patents that specifically define characteristics of the new invention and ensuring that the device does not infringe on licensed patents. Claims are the numbered paragraphs at the end of the patent that specify which features and technologies the inventor or firm hold (Yock et al., 2015).

Of the various types of technological void visualizations, an example of a tabular style patent map is a Technology-Function (T-F) table. Figure 2.5 displays a T-F table containing patents related to functions of a disposable endoscope. This patent map highlights technological gaps and potential areas of further R&D for an innovative disposable endoscope. The table contains patents listed by their IPC code linked to a patent brief containing a summary of the invention. The IPC codes are color-coded to show the patent's legal status.

Red: Expired Orange: Soon Expiring Blue: Active **Text: Potential Modification**		**Functions**								
		Prevent Infection/ Protection	Flexibility	Aided Perception			Portability	Aided Treatment		
				High Definition	Improved View	Full Camera Angle		Operation / Surgical Procedure	Extraction	Substance Delivery / Irrigation
	Endoscope Sheath	US5201908A US4522196A US4907395A US6537207B1 US4809678A US4920961A US10736655B1 US6997867B2	KR100971812B1 US10722103B2 US9055864B2 US6461294B1 US9155856B2 US20050250983A1 US7811228B2	extra clear sheath	US7311660B2 US20110257477A1	US6899672B2	US6908428B2	US7758497B2	Endscope sheath that works as a working channel for extraction of fluids from within the patient	US5386817A US20180353057A1
	Disposable Endoscope Sheath	US7481764B2 US5704892A US5402768A US4741326A US4869238A	KR102226947B1 CN202801687U US6383209B1 US9498108B1 US5483951A	extra clear sheath	US6126592A JP2011104383A	US6899672B2	easily stored away	US10307042B2	US8814781B2	US7811228B2 US5989183A US10342413B2
	Removable Parts	JP2008531175A US5498230A US5630782A US8485965B2	JP6197232B2 US7066880B2 US6802835B2 US7874980B2 US8317678B2	US9661986B2	CN112656345A US5163935A US8512232B2 US10278563B2	US6899672B2	CN112656345A	US8097003B2 US9560954B2 US5382255A US7608038B2 US9861264B2	US8591464B2 US9433340B2	US5693031A US6282442B1 US9227020B2 US9392929B2

Figure 2.5. Patent map for disposable endoscopes. (Xu et al., 2021)

On the other hand, a graphical type of patent map enables the visualization of voids in the patent landscape. In Figure 2.6, Lee et al. (2009) illustrated his findings on a graph where significant patent vacancies are circled in regions that lack numerically assigned patent data points. These circled regions showed technological voids deemed worthy of further research.

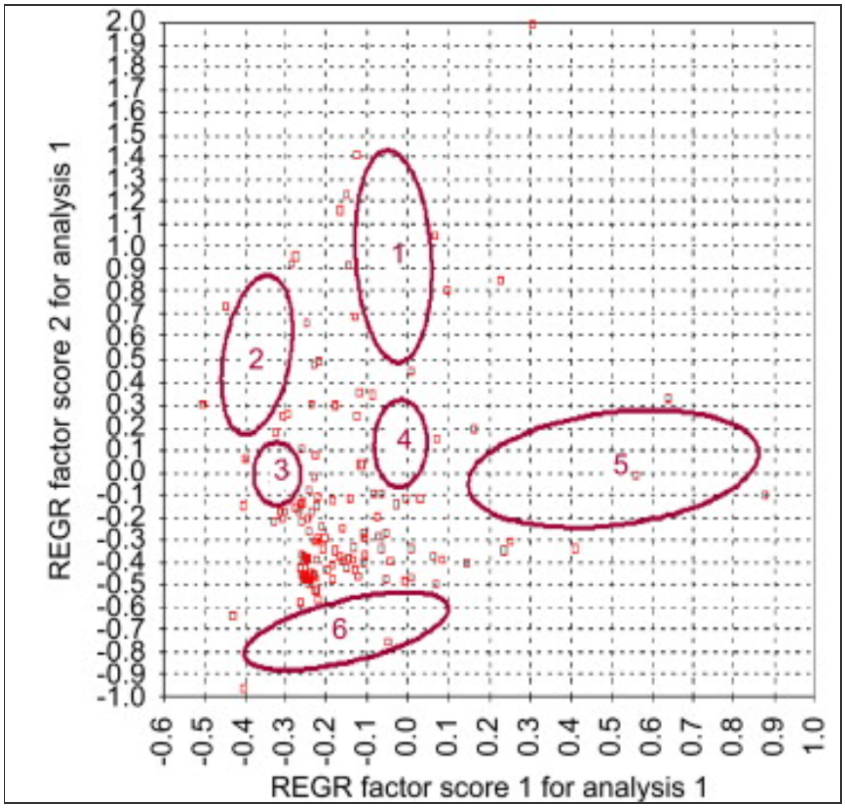


Figure 2.6. Patent voids extracted from keyword-based patent mapping. (Lee et al., 2009)

Recent increases in access to patent documents have facilitated econometric analysis of patent activity. The internationalization of patent protection, particularly in biomedical research, has promoted scientific innovation, foreign direct investment, and technological research (Oldham & Cutter, 2006). Gaps in the patent landscape provide an opportunity for research and innovation across the technological spectrum and promotes pursuit of IP as a wider process for "turning science into business" (Oldham & Cutter, 2006). A graphical view of patent citation relationships, types of patents, and classification codes helps researchers understand how a country's technology develops and spreads and exemplifies the researcher's ability to comprehend the mechanisms of knowledge transfer between technical domains, institutions, and countries (Cho & Shih, 2011).

While present information has shown that patent mapping is a useful method for finding gaps in the market, researchers and scholars have argued that patent regulation impairs biomedical R&D by blocking access to patented technologies. Known as the anti-commons problem, little evidence has been found of this problem in the biomedical field (Gold et al., 2010). In the US, public policy expert John Walsh conducted a survey and found that access to knowledge inputs is mostly unaffected by patents, showing how protected patents do not eliminate all research in the applied area (Gold et al., 2010). However, the protection granted by patents can cause an increase in the price of healthcare due to the additional funding in R&D required (Gold et al., 2010).

2.4 Intellectual Property Market & Public Policies in Taiwan

In recent decades, efforts to realize the potential in the Taiwanese patent market and IP regulations played a significant role in fostering innovation in Taiwan (Yang, 2008). In turn, this potential has the potential to bolster the economic success rate for businesses. A basic knowledge of IP is necessary to conduct R&D of an innovative technology within an increasingly proprietary industry.

IP is critical for growing businesses internationally, especially in high-tech industries where many Taiwanese companies operate (Yang, 2008). Taiwanese companies are aggressively applying for and acquiring patents to protect their technologies and increase revenue as the IP market in Taiwan continues to grow. Since the early 1990s, the Taiwanese government has made significant investments in R&D after recognizing the worth of IP and their lack of foreign patents in the market (Huang & Chang, 2010). From 1993 to 2006, Taiwan made continuous

efforts to acquire patents and nearly tripled the number of patents granted within that time frame (Huang & Chang, 2010).

The Industrial Technology Research Institute (ITRI) is Taiwan's largest government-sponsored industrial research institute. The institute's mission is to supplement Taiwan's high-tech industries by utilizing foreign patents; in doing so, they founded the Technology and Service Center in 2000 to concentrate on adding value to and commercializing ITRI's various technologies (Huang & Chang, 2010). Strategic patent infringement litigation and patent security are significant tactics in defining the shift from technological and legal approaches of the past to a modern commercial approach. In other words, patent infringement litigation has become more widely recognized as a tool for keeping corporate rivals in check (Park & Yoon, 2014).

A widespread misunderstanding is that a patent granted in one country provides protection across the world. However, a type of patent with truly international IP protections does not exist yet. The World Intellectual Property Organization (WIPO) aims to fill this gap by assisting patent applicants in obtaining the patent coverage needed on an international level (World Intellectual Property Organization, 2020). Currently, patents are granted by national governments and the protection they provide is confined to the country in which they are granted (Briggs, 2004). Patents protect tangible-good inventions and give their owners a legal binding right to prevent others from using the invention (Briggs, 2004).

Patent protection encourages companies to file more patents to strengthen their IP rights. In 1994, Taiwanese patent reform came as a result of the pressuring trade sanctions by Taiwan's international trading partners (Yang, 2008). Due to the rapid pace of technological change and

short product life cycles, the patenting behaviors of Taiwanese firms became more aggressive. With the goal of expanding international markets, Taiwan looked to block potential entrants to the patent pool and defend against patent infringement. As a result, these measures of patent security were found to encourage companies to file for more patents. As seen in Figure 2.7, a large spike in Taiwanese patent turnout occurred after 1994 suggesting that "[t]he upsurge in patenting by Taiwanese firms might be driven by the change in Taiwan's legal environment, which has ushered in stronger patent laws in their enforcement" (Yang, 2008). Additionally, further empirical models from Yang suggest the effect of strengthened intellectual property rights on patent volume, which "tend to lend evidence…that the upsurge in patenting by Taiwanese firms during the 1990s could plausibly be attributed to patent reform" (Yang, 2008).

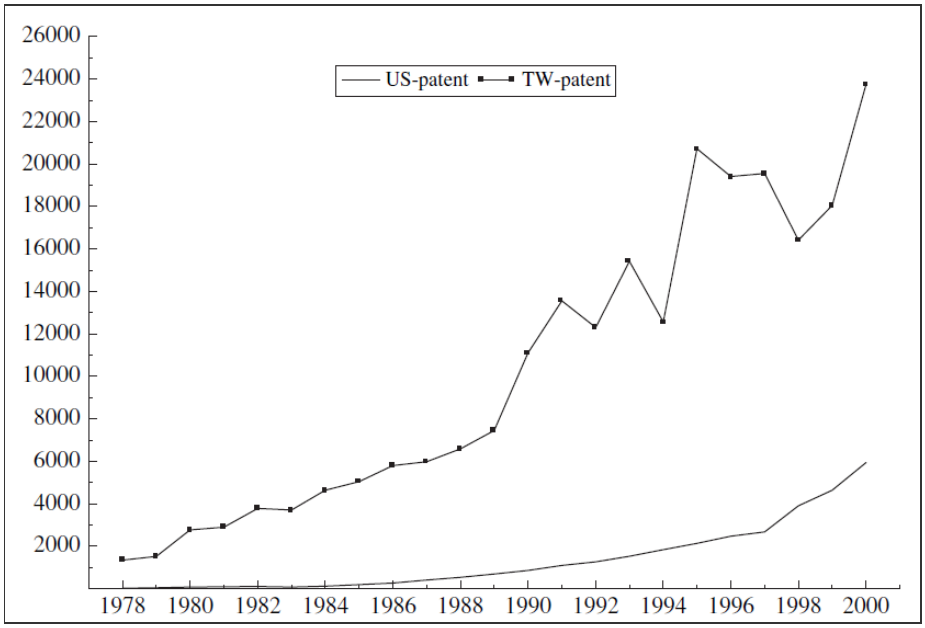


Figure 2.7. Number of patents granted in Taiwan vs. the United States. (Yang, 2008)

A dataset spanning 19 years shows the positive correlation between patent and export volumes exports in specific fields, which has been shown to be a good indicator of patent value

to corporations (Frietsch et al., 2014). Considering that Taiwan is already at the forefront of the biotech industry, evidence indicates that Taiwan's developmentalist approach to the economy along with their patent market and intellectual property laws has paid off (Wong, 2016). A developmentalist approach operates with the goal to transition from a "strong government - weak civil society" to a "strong government - strong civil society", enabling the developing state to grow and achieve economic success (Kim, 2020). The definition of the approach is having economic development as a national policy goal, government involvement in the market, and/or elites exerting influence on policy making (Kim, 2020).

Currently, Taiwan is a significant market for medical device exports from the United States. In 2020, Taiwan's medical equipment market reached US$4.3 billion, according to estimates from the International Trade Administration (International Trade Administration, 2021). Products from the United States and Taiwan's neighboring countries, particularly mainland China and other low-cost producers, are strongly represented in the market. Taiwan is an excellent market for high-quality, differentiated products as well as commodity ones. In Taiwan's market, high-end medical equipment gives the largest possibility for imports: imports account for over 70% of the market, with the United States accounting for around 32% of the market (International Trade Administration, 2021). The expansion of Taiwan's digital healthcare sector is one of the country's primary goals in the next few years. Thus intellectual property rights holders cite both positive and negative trends in Taiwan's intellectual property protection and enforcement. Taiwan has improved its trade secret protection and enforcement in recent years (International Trade Administration, 2021). On the other hand, combating copyright and

related infringement in both online and printed instructional resources remains a significant concern.

Additionally, public policy for patent protection plays a vital role in promoting technological innovation. Some examples of these policies include “federal regulation, product liability statutes, reimbursement rules, and government funding” (Foote, 1991). Since obtaining protection in all significant markets can be extremely expensive—hundreds of thousands of dollars in some cases—ideas patented in the U.S. may be unfeasible to patent in other nations. A new technology patented in the U.S., but not in Taiwan, would only be fully protected in the U.S. Importing a product containing the protected IP or items arising from a patented process into the United States could face legal challenges (Briggs, 2004).

2.5 Sponsor Background

Summed Taiwan is a medical technology incubation platform and venture capital company founded by President Yi-Ping Hong in 2017. Summed Taiwan currently supports a number of medical startups in its portfolio including CUUMed, COATMED, Maxima Biotech, HCT Regenerative, and IIA Chen (Summed Taiwan, 2022). The company sees Taiwan’s supply chain and medical device technology innovation as a promising base for the mass production of medical instruments on a global scale. With over 100 members in their network, Summed Taiwan encourages investors, professional groups, and marketing partners to share their vision to help bolster the medical device industry in Taiwan (Summed Taiwan, 2022).

When supporting the development of a new medical device, Summed Taiwan conducts feasibility studies on the chosen technology, channels resources to motivate product development, and implements an organizational structure into an incubated startup. One of the

most valuable resources Summed Taiwan provides are their bio-managers. After selecting a startup for investment, Summed Taiwan assigns the startup a bio-manager specializing in the field of development. With twenty bio-managers with backgrounds ranging from former directors of major medical corporations to attending doctors at Taiwanese hospitals, Summed Taiwan's expert modules are a key asset in accelerating product development (Summed Taiwan, 2022). Figure 2.8 shows a representation of the connection between investors, innovators, and expert modules within the company.

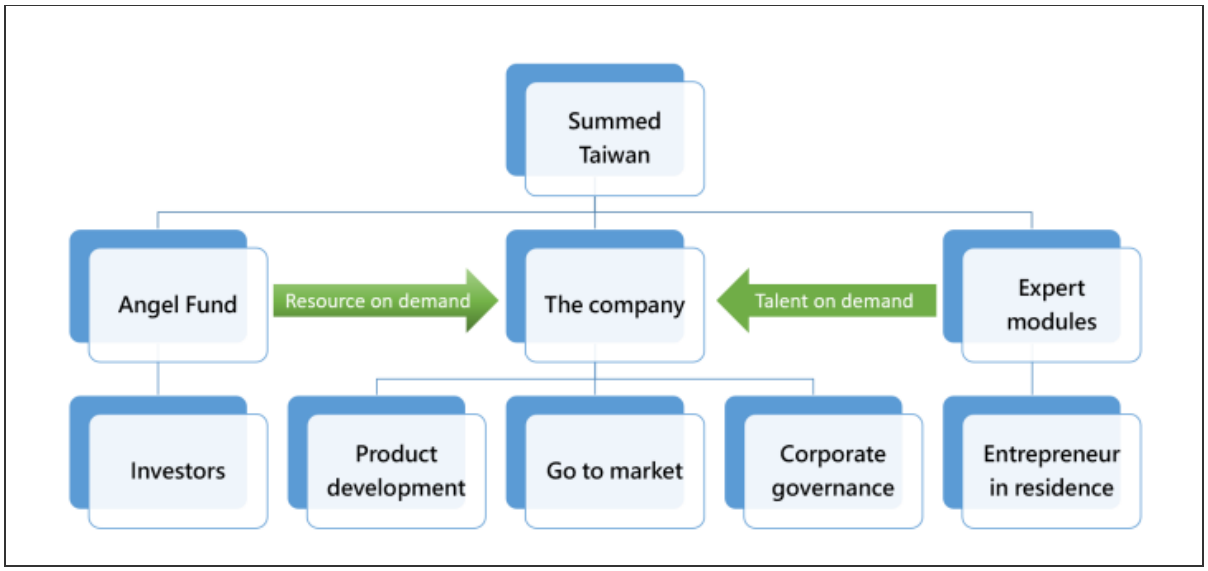


Figure 2.8. Summed Taiwan's structure for incubating a startup company.

(S. Yeh, personal communication, 2022)

Summed Taiwan is currently invested in the development of two other medical device technologies besides surgical staplers: an ultrasonic scalpel and a disposable endoscope (S. Yeh, personal communication, 2022). In 2021, Summed Taiwan began collaborating with WPI on an Interactive Qualifying Project (IQP) focused on developing a patent map for the innovative disposable endoscope (Xu et al., 2021).

With surgical staplers as their next major area of focus for R&D and investment, the company seeks to ensure the profitability and mass production of an innovative surgical stapler. As a VC company in the medical device industry, Summed Taiwan's capital will play "an important role in the next stage of the innovation life cycle—the period in a company's life when it begins to commercialize its innovation" (Zider, 1998). Figure 2.9 depicts the many different stakeholders with respective needs or interests relevant to the development of a novel medical technology.

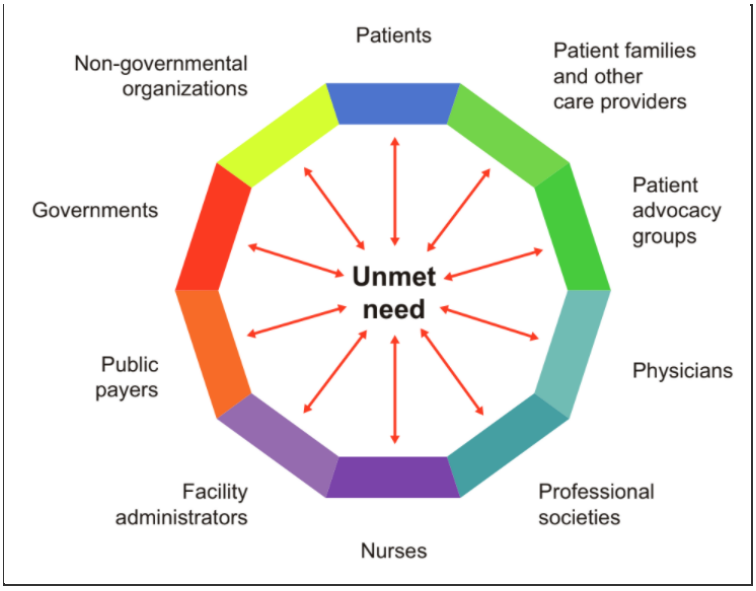


Figure 2.9. Potential stakeholders in a new medical technology to solve a specific problem. (Yock et al., 2015)

2.6 Summary

The purpose of this review was to gain insight on patent mapping techniques, with a focus on trends for improving existing surgical stapler technologies and possibly developing new ones. Patent mapping exists at the root of innovation through various methods of data processing

with applications in the R&D of medical technologies. It is important to consider patent infringement and Taiwan's patent market in order for patent maps to successfully assimilate into the medical industry. Many of the same economic pressures that affect other highly innovative businesses also affect the medical device industry, with new patents that are issued to large corporations instead of smaller startup companies. Commercialization is influenced by patent processes and public policies. The overview provided serves as the framework for the project on the technicalities of patent mapping in the realm of science, public policies, intellectual property regulations, economic implications, and Taiwan's current patent market. These technicalities are essential for Summed Taiwan to forecast the best avenue for investment through an FTO analysis. The research team estimated the risks of patent infringement by developing the patent map for Summed Taiwan to help warrant further R&D of surgical stapler technologies.

3.0 Methods

The goal of this project was to assist Summed Taiwan with their feasibility study and lay the groundwork for FTO patent analysis for an innovative surgical stapler end effector (cartridge) design. The team accomplished this goal through the following objectives:

1. Identified stapler functions, key features, and technical terms in patents to create an initial Technology-Function (T-F) table.
2. Applied Boolean grammar to filter and acquire data from patent databases to create patent briefs and an improved T-F table.
3. Conducted interviews with medical device and legal professionals to inform the team's understanding of the surgical stapler market and legal principles.
4. Utilized T-F table (patent map) to identify opportunities in the patent landscape for improvements.

Before developing a new surgical stapler technology, inventors and investors must first identify and comprehend the opportunities and technological voids in their area of study. The team utilized a combination of archival research and interviews to identify the legal challenges and social implications of designing a novel surgical stapler. The team collected and organized data from interviewing experts in the medical device and legal fields (video calls), archival research (patent databases and Boolean search strategy), and patent briefs to create the patent map (T-F table). The following sections outline each methodological approach to creating the patent map for Summed Taiwan's FTO analysis of surgical stapler cartridges.

3.1 Interview Research

The team conducted interviews with biomedical professors, medical device experts, and legal experts to inform the social implications of medical device innovation. The team developed semi-structured interview guides for each type of interview (located in Appendices A–C) to gain

a better understanding of key topics as research progressed. During these interviews, the team also solicited feedback on the Boolean search strategy, gathered insight on the challenges presented by intellectual property regulations, and obtained unique perspectives on the development of surgical staplers and medical device investment.

The team interviewed a medical device expert, patent search engine developer, Taiwanese surgeon, former Johnson & Johnson surgical stapler salesperson, WPI biomedical professors, and the WPI Director of Technology Commercialization. The team scheduled virtual Zoom interviews in the time zone of the interviewee. Conducting interviews impartially, avoiding leading questions. Additionally, performing interviews in a way that maintained the integrity of the information while treating the interviewee with respect, while protecting the interviewee's privacy (Berg & Lune, 2017). The team created transcriptions of each interview for further analysis and record-keeping purposes. During interviews, the team utilized laptops, cameras, microphones, and headphones to collect data. All interviewees consented to the recording of interviews and gave permission for the researchers to publish names. The team used Zoom's built-in recording transcription tools and took thorough notes during interviews to ensure a complete record for analysis.

3.1.1 Medical Device Expert Interviews

The team connected with a former surgical stapler salesperson and a Taiwanese surgeon through Dr. Yeh to obtain a modern perspective on the device's utility. The team interviewed Dr. Wei-Hsun Lu, an attending physician in the department of general surgery at National Cheng Kung University Hospital in Tainan, Taiwan. The primary purpose of interviewing a surgeon was to acquire a first-hand account of common challenges faced when operating surgical staplers.

The team also interviewed Frank Chen, a former salesperson now working at Summed Taiwan, who has over ten years of experience selling surgical staplers manufactured by Ethicon Inc. The interview with Mr. Chen helped the team understand the current surgical stapler market, along with major design considerations and historical issues when developing innovative surgical staplers. In terms of ethical considerations, we avoided direct questions related to medical patients to protect patient privacy. Questions for these interviews focused on prior experience, IP regulations and public policy, and common issues and complaints. Appendix A contains the specific guide for medical device expert interviews.

3.1.2 Biomedical Professor Interviews

The team interviewed WPI professors Leonard Polizzotto, Ph.D. and Yihao Zheng, Ph.D. due to their expertise in researching, developing, and teaching about medical devices. As an Assistant Professor in the Mechanical Engineering department with affiliations to Biomedical and Robotics Engineering, Zheng's research focuses on medical manufacturing and innovation. Professor Zheng kindly provided the research team with materials from his course at WPI on Medical Device Innovation and Development, which informed the team's literature review on patentability. The interview with Professor Zheng provided the research team with a new perspective on the academic setting for medical device R&D, the patenting process, and how to avoid prior art infringement. The team also interviewed Professor Leonard Polizotto, an Electrical and Computer Engineering professor at WPI with past experience working at Draper Laboratories and with biomedical devices in Taiwan. Professor Polizotto shared his expertise in building value propositions and stakeholder identification when developing a new product. Questions for these interviews focused on prior experience, patent application and search

processes, medical device development, and IP regulations and public policy. Appendix B contains the specific guide for biomedical professor interviews.

3.1.3 Legal Expert Interviews

In order to gain a thorough understanding of intellectual property, FTO analysis and limitations, and the patenting process, the team interviewed legal expert Todd Keiller, WPI Director of Technology Commercialization. With 20 years of experience in the technology transfer field, Mr. Keiller has extensive experience in helping research labs patent innovative biomedical devices. His expertise helped the team navigate the complex field of regulations and restrictions on patents.

Mr. Keiller also connected the team with Peter Fenner, a WPI class of ‘64 alumnus and creator of the SearchRealFast.com patent search engine. He introduced the team to The Lens (or lens.org)—a patent database used in the SearchRealFast.com search engine with unique graphical visualizations of patent-related data and showed the team how to utilize the website’s filters. Questions for these interviews focused on IP regulations and public policy, FTO analysis, along with patent application and search processes. Appendix C contains the specific guide for legal expert interviews.

3.2 Patent Archival Research

To create an initial Technology-Function table, the team conducted archival research into existing patents related to the development of the end effector (otherwise known as the distal end) of linear surgical staplers. Patents help safeguard inventions and protect any product, design, or process that meets certain specifications according to its originality, practicality,

suitability, and utility. Archival research focused on function identification, including primary components of the device and major technical terms common throughout surgical stapler patents. The team accessed patent data through online-databases including Google Patents, The Lens, and Taiwan's Global Patent Search System (GPSS). A representative patent research process is outlined in Figure 3.1.

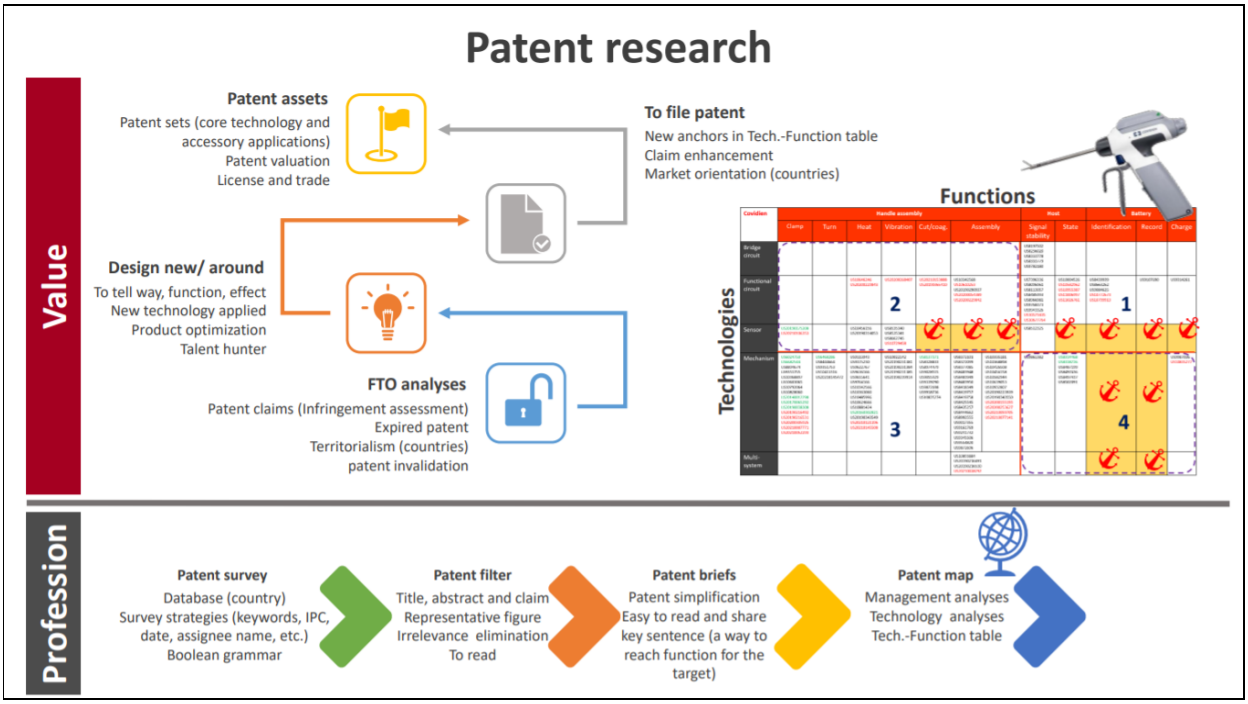


Figure 3.1. Patent research process map. (S. Yeh, personal communication, 2022)

The sponsor provided a single representative patent, US7000818B2, to extract domain knowledge, features, technical terms, and keywords to begin outlining the T-F table. With these extracted data, the team constructed an initial T-F table which informed initial patent searches. The team conducted searches using Google Patents, The Lens, and GPSS, gradually refining the T-F table categories. The team's initial stage of patent research played a critical role, setting the scope of information that the table can sort.

Search databases such as Google Patents, The Lens, and GPSS allow users to view several patent publications of interest in the technology or topic of interest in relation to surgical staplers. These databases allow users to type the publication number of a specific patent application or do a general search on a specific technology in the search bar. For example, when researching the patent publication US7000818B2, the team typed out the publication number into Google Patents' search bar and then selected the first proposal that appears as shown in Figure 3.2.

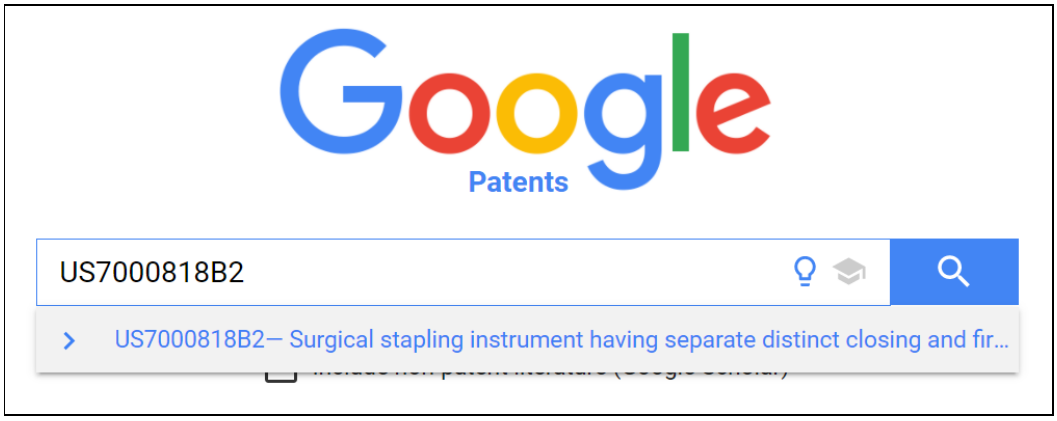


Figure 3.2. Example patent publication search using Google Patents.

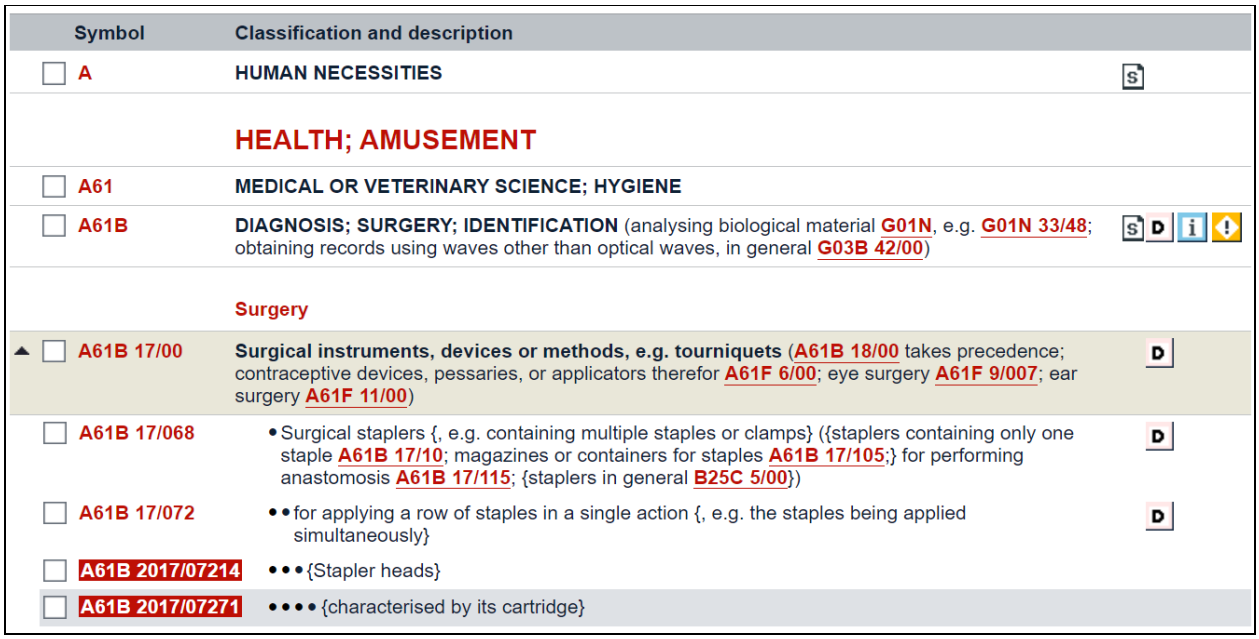
As recommended by the sponsor and previous IQP that worked with Summed Taiwan, the team initially used Google Patent and GPSS as the search engines of choice. However, after Peter Fenner displayed the Lens' powerful search and visualization capabilities during our interview, the team switched to that as the primary patent search database.

3.2.1 Search Strategy

Key technologies and features extracted from the representative patents allowed the team to use an iterative Boolean search strategy to obtain patents relevant to the end effectors of surgical staplers. The team used a Boolean strategy since it is the top keyword processing and

text mining strategy (Noh et al., 2015). The text search normally begins with terms that describe the idea, combining these keywords with Boolean logic operators like "AND" and "OR" to considerably increase the search's precision (Yock et al., 2015). It can also be useful to search for notable inventor names in the field, assignees (the business that owns a specific patent), and competitor companies.

The team created an initial search query for use with The Lens's patent database, "surg* AND stapl*". As denoted by the asterisks in the search term, this initial search looked for any patents in the database containing words starting with "surg" and "stapl" (e.g., "surgical stapler" or "stapling surgery"). This initial search query returned over 100,000 patents—a large number of patents, not feasible to analyze within the scope of this project. Thus, Summed Taiwan requested the team narrow the search. The team next looked for patents belonging to either Ethicon Inc. or Covidien, two companies that comprise over 90% of the surgical stapler market in Taiwan (F. Chen, personal communication, 2022). The search query "surg* AND stapl* AND (applicant.name:ethicon* OR applicant.name:covidien*)" limited the search to patents applied for by either of those two companies, using the Boolean OR operator, reducing the results to around 24,000 patents. Using The Lens's patent search analysis tools, the team determined that the IPC classification A61B2017/07271 was suitable for further limiting the search, as it encompasses all patents related to surgical staplers characterized by their cartridges. Figure 3.3 shows the specific breakdown of each component of the IPC classification (Espacenet, 2019). This additional filter prevented the search from returning patents relating to non-surgical staplers while also specifying a focus on cartridges, bringing the query results down to 8,268 patents.



Symbol	Classification and description
A	**HUMAN NECESSITIES**
	HEALTH; AMUSEMENT
A61	**MEDICAL OR VETERINARY SCIENCE; HYGIENE**
A61B	**DIAGNOSIS; SURGERY; IDENTIFICATION** (analysing biological material G01N, e.g. G01N 33/48; obtaining records using waves other than optical waves, in general G03B 42/00)
	Surgery
A61B 17/00	**Surgical instruments, devices or methods, e.g. tourniquets** (A61B 18/00 takes precedence; contraceptive devices, pessaries, or applicators therefor A61F 6/00; eye surgery A61F 9/007; ear surgery A61F 11/00)
A61B 17/068	• Surgical staplers {, e.g. containing multiple staples or clamps} ({staplers containing only one staple A61B 17/10; magazines or containers for staples A61B 17/105;} for performing anastomosis A61B 17/115; {staplers in general B25C 5/00})
A61B 17/072	•• for applying a row of staples in a single action {, e.g. the staples being applied simultaneously}
A61B 2017/07214	••• {Stapler heads}
A61B 2017/07271	•••• {characterised by its cartridge}

Figure 3.3. IPC breakdown for A61B2017/07271. (Espacenet, 2019)

With the search limited to surgical stapler cartridges, the team began to iterate on the Boolean search strategy, using the keywords extracted from the representative patent as shown in Figure 3.4 and Table 3.1. The iterative process shown in Figure 3.4 was an early iterative search strategy used by the team in GPSS. Later search strategies used The Lens as shown in Table 3.1.

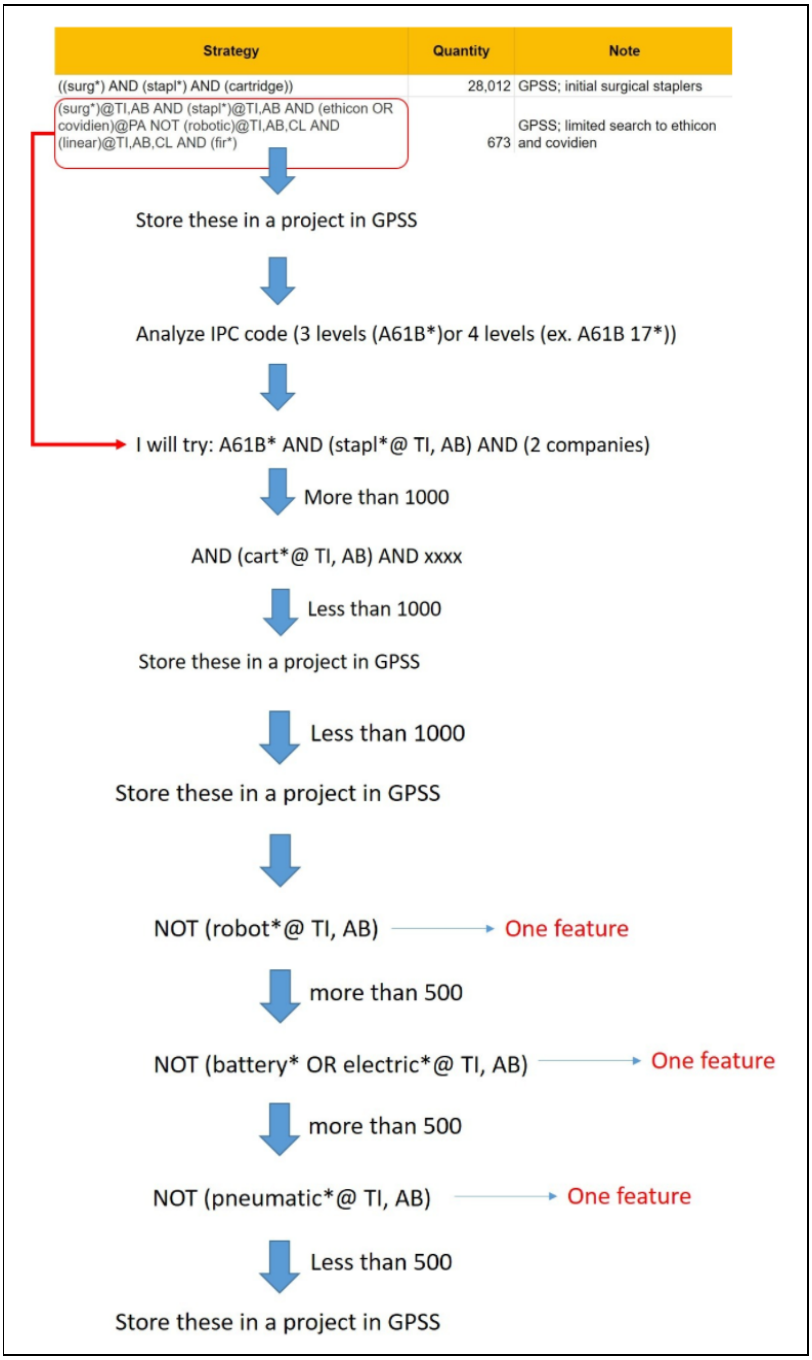


Figure 3.4. Instructions on refining search query. (S. Yeh, personal communication, 2022)

Table 3.1. Iterations of Boolean search query using The Lens.

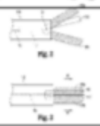
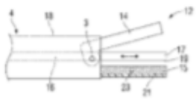
Search Query	Filter	Quantity	Note
surg* AND stapl*		105,394	The Lens; initial surgical stapler search
surg* AND stapl* AND (applicant.name:ethicon* OR applicant.name:covidien*)		24,408	Limit to Ethicon or Covidien
surg* AND stapl* AND (applicant.name:ethicon* OR applicant.name:covidien*)	CPC Classification Code = (A61B2017/07271)	8,268	Limit to A61B2017/07271 (surgical stapler cartridges)
(title:(surg* AND stapl*) OR abstract:(surg* AND stapl*) OR claim:(surg* AND stapl*)) AND (applicant.name:ethicon* OR applicant.name:covidien*)	CPC Classification Code = (A61B2017/07271)	6,425	Refine surg* and stapl* to title, abstract, or claims
(title:(surg* AND stapl*) OR abstract:(surg* AND stapl*) OR claim:(surg* AND stapl*)) AND (applicant.name:ethicon* OR applicant.name:covidien*)	CPC Classification Code = (A61B2017/07271); Application Filing Date = (2002-01-01 -)	6,410	Exclude patents older than 2002 (hoping to exclude expired patents)
(title:(surg* AND stapl* AND cart*) OR abstract:(surg* AND stapl* AND cart*) OR claim:(surg* AND stapl* AND cart*)) AND (applicant.name:ethicon* OR applicant.name:covidien*)	CPC Classification Code = (A61B2017/07271); Application Filing Date = (2002-01-01 -)	5,064	Limit to cartridges
(title:(surg* AND stapl* AND cart* AND linear*) OR abstract:(surg* AND stapl* AND cart* AND linear*) OR claim:(surg* AND stapl* AND cart* AND linear*)) AND (applicant.name:ethicon* OR applicant.name:covidien*)	CPC Classification Code = (A61B2017/07271); Application Filing Date = (2002-01-01 -)	308	Limit to linear staplers
(title:(surg* AND stapl* AND cart* AND linear* AND fir*) OR abstract:(surg* AND stapl* AND cart* AND linear* AND fir*) OR claim:(surg* AND stapl* AND cart* AND linear* AND fir*)) AND (applicant.name:ethicon* OR applicant.name:covidien*)	CPC Classification Code = (A61B2017/07271); Application Filing Date = (2002-01-01 -)	204	Limit to patents related to firing
(title:(surg* AND stapl* AND cart* AND linear* AND fir*) OR abstract:(surg* AND stapl* AND cart* AND linear* AND fir*) OR claim:(surg* AND stapl* AND cart* AND linear* AND fir*)) AND (applicant.name:ethicon* OR applicant.name:covidien*)	CPC Classification Code = (A61B2017/07271); Application Filing Date = (2002-01-01 -); Legal Status = Active, Pending)	188	Limit to Active or Pending Patents
(title:(surg* AND stapl* AND cart* AND linear* AND fir* NOT microneedle*) OR abstract:(surg* AND stapl* AND cart* AND linear* AND fir* NOT microneedle*) OR claim:(surg* AND stapl* AND cart* AND linear* AND fir* NOT microneedle*)) AND (applicant.name:ethicon* OR applicant.name:covidien*)	CPC Classification Code = (A61B2017/07271); Application Filing Date = (2002-01-01 -); Legal Status = Active, Pending)	181	Remove microneedles
(title:(surg* AND stapl* AND cart* AND linear* AND fir* NOT microneedle* NOT circuit*) OR abstract:(surg* AND stapl* AND cart* AND linear* AND fir* NOT microneedle* NOT circuit*) OR claim:(surg* AND stapl* AND cart* AND linear* AND fir* NOT microneedle* NOT circuit*)) AND (applicant.name:ethicon* OR applicant.name:covidien*)	CPC Classification Code = (A61B2017/07271); Application Filing Date = (2002-01-01 -); Legal Status = Active, Pending)	170	Remove circuit
(title:(surg* AND stapl* AND cart* AND linear* AND fir* NOT microneedle* NOT circuit*) OR abstract:(surg* AND stapl* AND cart* AND linear* AND fir* NOT microneedle* NOT circuit*) OR claim:(surg* AND stapl* AND cart* AND linear* AND fir* NOT microneedle* NOT circuit*)) AND (applicant.name:ethicon* OR applicant.name:covidien*)	CPC Classification Code = (A61B2017/07271); (Legal Status = Active, Pending)	170	Remove filter for date (redundant with Active Patents)
(title:(surg* AND stapl* AND cart* AND linear* AND fir* NOT microneedle* NOT circuit*) OR abstract:(surg* AND stapl* AND cart* AND linear* AND fir* NOT microneedle* NOT circuit*) OR claim:(surg* AND stapl* AND cart* AND linear* AND fir* NOT microneedle* NOT circuit*)) AND (applicant.name:ethicon* OR applicant.name:covidien*)	CPC Classification Code = (A61B2017/07271);	185	Removed filter for active and pending patents (Sam suggested we do not exclude expired patents); added 3 non-duplicates

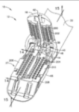
3.2.2 Patent Briefs

Patent documents provide a wide array of data for analysis; such information requires a degree of expertise in information retrieval, domain-specific technologies, and business

intelligence (Abbas et al., 2014). Patent documents are often lengthy and consist of various technical and legal terminology. Therefore, the team needed to condense these documents into individual patent briefs which simplify and highlight key information from patent documents. Patent informatics is the process of examining patent data using automated tools to uncover patent intelligence through visualization, citation analysis, and other approaches such as text mining. With these text mining and visualization techniques, our team was able to coherently parse through patents in our patent map. The task of parsing unstructured data necessitates the use of extraction techniques and automated tools that can split textual data into understandable structures. Text mining technologies are also utilized for patent visualization techniques to convey the results of a patent study in a visual format. Since patent documents are made up of several sections (abstract, figures, patent function, additional research), each of which has its own set of differentiating qualities based on its purpose, the team needed to identify the parts of the documents we wanted to extract keywords, such as the component or patent function. Standardized patent data is crucial for the structured outcome to be consistent and understandable (Noh et al., 2015).

As patents contain both structured and unstructured data, the team summarized segments of patent briefs to produce a succinct representation, making it easier for future analysts to share and reuse the examined patents. The narrative text in the unstructured patent data includes the patent title, abstract, claims, and description. The structured patent data includes information such as the patent's inventor, licensee, and citation information. A functional and legible patent brief includes patent number, title, one sentence to describe feature/technology and function, figure, and expired brief. Figure 3.5 shows example patent briefs.

	Patent No.	Title	One sentence	Figure	Expired date
56	US9351753	Ultrasonic medical instrument with a curved waveguide	含螺旋移動元件的彎曲waveguide		2034
57	US9351755	Ultrasonic surgical instruments	夾爪合起時，第一夾爪被包在第二夾爪內		2032/部分2031
58	US9375230	Ultrasonic surgical instruments	具散熱和隔熱的第二夾爪		2033/部分2031
59	US9554820	Ultrasonic surgical instrument	刀桿結合組裝包含一個扭力連結器		2032/部分2031

Patent No.	Title	One sentence	Figure	Expired date
US7000818	Surgical stapling instrument having separate distinct closing and firing systems			2023

A firing bar with upper member to clamp tissue stably.

Figure 3.5. Patent brief examples. (S. Yeh, personal communication, 2022)

After completing a patent brief, the next step is to create a patent map that served as a rapid catalog for the briefs. Each patent brief has an individual patent number and the patent map is a list of these patent numbers, organized by function and technology. The results of unstructured patent data are represented in the patent briefs. The patent map is a tool that visualizes the relationships between patents, described in patent briefs, by building maps using keywords and key phrases. With patent briefs compiled, the team followed the described workflow (Figured 3.6) to organize and extract data for analysis.

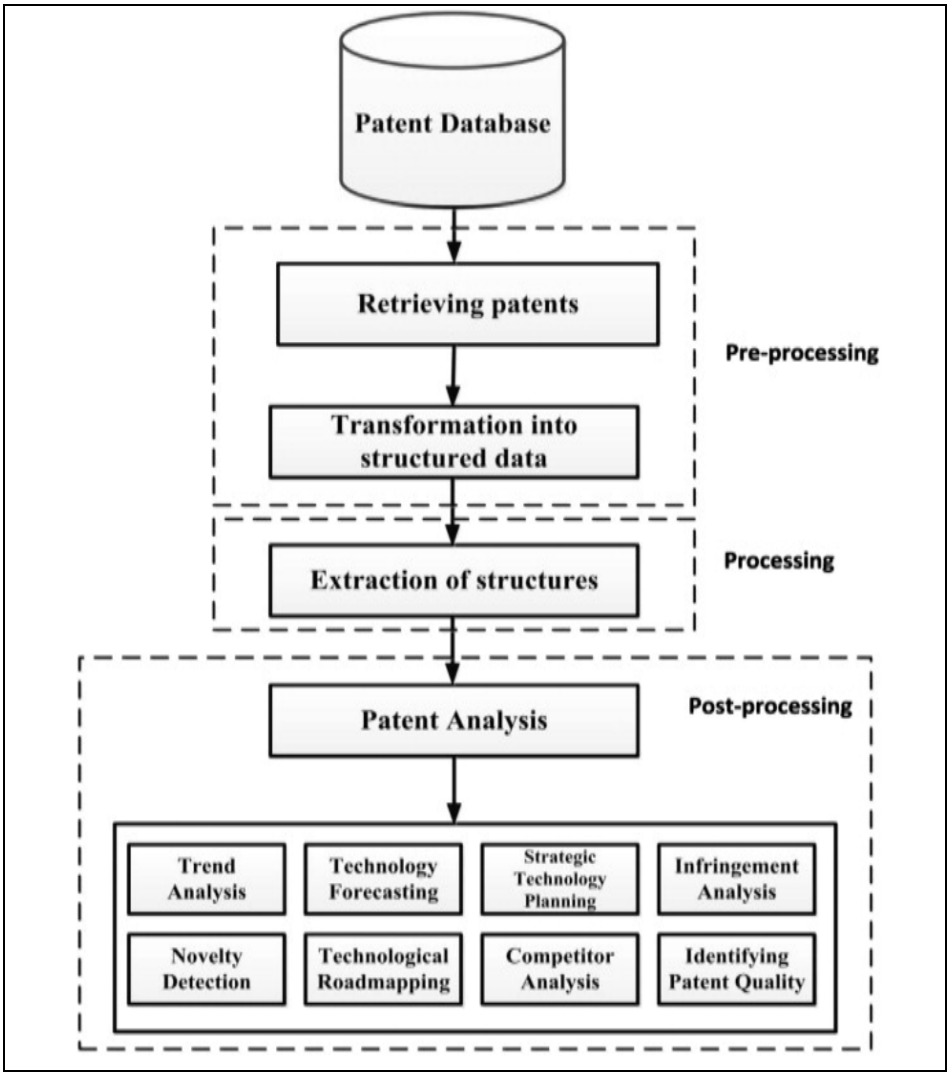


Figure 3.6. Generic patent analysis workflow. (Abbas et al., 2014)

Patent research is useful for establishing the validity of a company's inventions as well as detecting the competitors' IP and technological competitiveness. Aside from providing technological competitiveness, IP information can also forecast a company’s future development. Patent analysis studies evaluate the relationship between technological advancements and economic progress (Abbas et al., 2014).

The cornerstone objective of the team's project is the creation of a T-F table/patent map. Using initial technologies and functions determined from preliminary patent research, the team researched patents and created patent briefs. With advice from our sponsor, the patent-brief table included the following:

- Patent Number or ID
- Patent Title
- Application Date
- Publication Date
- Expiration Date
- Owner
- Abstract
- Country
- CPC/IPC and/or US Classifications

Conducting this initial patent research enabled the team to efficiently parse relevant patents to include in our Technology-Function table, or patent map.

3.2.3 Technology-Function (T-F) Table

Patent data comes with documentation vital to research findings useful to industries, businesses, legal communities, and policymakers. Patent maps such as T-F tables expose technological subtleties and relationships, reveal business trends, stimulate creative industrial solutions, or assist in the formulation of investment strategies when constructed with relevant, desired technologies and functions. Our research team recognized that existing types of patent maps and techniques, while satisfactory, had room for further optimization in helping identify technological gaps and areas of infringement in medical devices. The team chose to create a tabular keyword-based patent map to visualize technological voids in the surgical stapler market, ensuring completion of project deliverables within the scope of the project's timeline and research team's skills sets.

The method for achieving the first objective was the creation of an initial T-F table. The table consists of two axes: technologies and functions. The technology axis consists of the major subsystems of the device. Figure 3.7 breaks down the major technologies of an ultrasonic dissector into Bridge Circuit, Functional Circuit, Sensor, Mechanism, and Multi-system. On the other axis of the table are the functions of the device. These functions are major assemblies broken down into specific characteristics, such as Handle Assembly, broken down further into Clamp, Turn, Heat, Vibration, Cut/Coag., and Assembly. A patent's IPC code occupies the cell which intersects the axial position of the technology and function of its claimed invention.

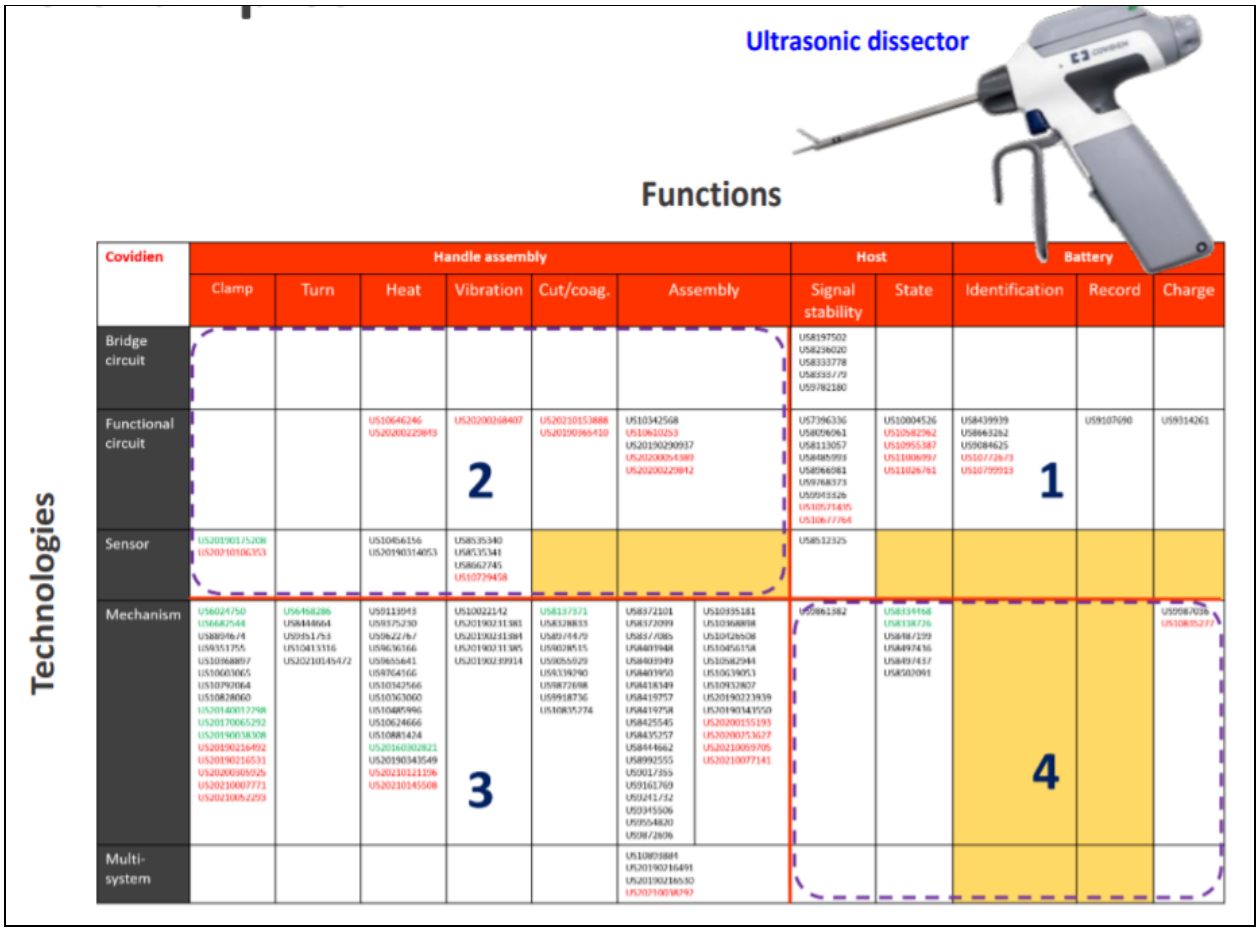


Figure 3.7. Example of Technology-Function table. (S. Yeh, personal communication, 2022)

The technological similarity between patents is a significant aspect in determining the potential of patent infringement; the target product should address the related patents, both expired and active, as well as design around those active patents. In creating the T-F table, the team was able to accurately display the current surgical stapler technologies and functions patented for Summed Taiwan to continue their FTO analysis for future investments.

3.3 Limitations

Analyzing patent documents requires an extensive level of expertise. The team parsed through vast amounts of data and analyzed hundreds of patents. Given the volume of patents encountered, it is possible the team missed patents with the search query which may raise legal concerns for patent infringement. Unfortunately, most human-based data mining methods are incapable of handling massive amounts of information. Furthermore, because most data mining approaches are algorithmic rather than data-driven, there is currently minimal synergy between data mining and data warehouses (Tseng et al., 2007). Although archival data is a great source of primary material, it typically contains several faults including selection bias (Berg & Lune, 2017). Another limitation in the research was correctly identifying each patent's technology and functionalities. It was critical to articulate the main features and functionalities of each patent to construct a practical surgical stapler from previous designs.

While there are a multitude of patents on the market in databases, time constraints limited the number of patents and research the team was able to assess. To mitigate this limitation, we implemented a more concise search for specific types of surgical staplers, such as powered or unpowered staplers and the limitation to the cartridge portion of surgical staplers.

When consulted on common problems with IP regulations and patents, Todd Keiller, WPI Director of Technology Commercialization, stated “the biggest problem is prior art” (T. Keiller, personal communication, 2022). In a separate interview, Professor Zheng commented that prior art can be described as “existing literature, website and everything [else…]”, making the scope of a full FTO analysis vast (Y. Zheng, personal communication, 2022).

Discussions regarding searching for prior art helped inform the development and marketing of new products, as well as the limitations of the financial implications of infringement. Patent attorneys are best suited for this type of analysis since they are familiar with the IP laws in effect in a specific nation and typically have access to commercial patent databases that allow for a credible search in the state of the art (Y. Zheng, personal communication, 2022). Such assessments are worthwhile to commission to ensure efficiency when applying for patents (patentability examination) and to reduce the risk of third parties suing for patent infringement (FTO search) on another inventor’s exclusive rights. This leads into the main limitation for our team in performing this preliminary FTO analysis. As the research team holds a background in engineering and lacks the legal knowledge necessary to perform a full-fledged FTO analysis, our team focused on conducting a preliminary analysis. Thus, these limitations motivated the team to reduce the project scope for the FTO analysis and provide the base groundwork for a future comprehensive FTO assessment.

Interviews were another source of limitations. For example, interviewing legal experts had the limitation of lack of expertise in the surgical stapler market. The legal experts interviewed were not practicing patent attorneys. A limitation with interviewing medical professionals and WPI Biomedical Professors was that their knowledge may be limited to a

specific type of surgical stapler used in their practice or research and not necessarily be indicative of the entire market, or even a lack of experience with surgical staplers as a whole.

Finally, a limitation of creating this T-F Table was not knowing what products might be under development, but not patented. Patents are good at showing existing technologies and those in the final stages of development—they are delayed from the actual R&D process of companies. To mitigate this limitation, in our research and interviews we used current patents to determine potential shortcomings of the surgical stapler market to help predict upcoming technological developments.

4.0 Results & Analysis

Through analysis of data collected via interviews and archival research, the team identified five major findings. First, the team obtained knowledge on the significance of surgical stapler innovation in Taiwan from economic and medical perspectives. Second, the team identified issues with current surgical staplers that motivated Summed Taiwan to research and develop a new stapler design. Third, the team clarified the role of an FTO analysis during the patenting process, the characteristics of a patentable invention, and limitations of the team's research. Fourth, the team developed a patent search strategy for identifying prior art on surgical stapler cartridges and discovered useful online visualization tools. Lastly, the team created the patent briefs and T-F table, and used these tools to find technological voids in the surgical stapler market. The following chapter presents the research findings of the team across the two primary methodologies for the project.

4.1 Social Implications of Surgical Stapler Innovation in Taiwan

Utilizing both economic and medical perspectives, the team acquired knowledge on surgical stapler innovation in Taiwan and its significance beyond monetary return. Currently, the surgical stapler market in Taiwan is a duopoly between J&J's Ethicon Inc. and Medtronic's Covidien. While there are several other companies such as Intuitive Surgical in the market, former surgical stapler salesperson for Ethicon Inc. and current biomanager at Summed Taiwan, Frank Chen, described the market as an almost 50-50 split between these two companies (F. Chen, personal communication, 2022).

While Taiwan displays a prominent history as a leader in the electronics market, the country's influence in the medical devices market remains in the growth stage. With Taiwan's developmentalist economy, Summed Taiwan's focus on innovations within the biotechnology sector is in line with a developmental state and is "embedded within productive sectors of society" (Wong, 2016). With only two major competitors existing in the development of surgical staplers, the market is opportunistic (F. Chen, personal communication, 2022). Nevertheless, discussions with Dr. Yeh and Frank Chen from Summed Taiwan revealed to the team that Summed Taiwan aims to join the current set of reigning multinational corporations as a major player in the surgical stapler market (F. Chen, personal communication, 2022).

4.2 Technical Issues with Current Surgical Staplers

The team interviewed promoters and operators of current surgical staplers on the market to identify major mechanical and operative issues motivating Summed Taiwan's development of a new surgical stapler. These interviews provided a first-hand perspective that supplemented the team's literature review on FDA surgical stapler recalls and reports on the dangers of staplers. In the team's interview with Dr. Wei-Hsun Lu, the team acquired feedback on design challenges with operating surgical staplers. Having expertise performing gastrointestinal and emergent types of surgery, Dr. Lu utilizes surgical staplers everyday and points to them as a critical tool when conducting transection or anastomosis.

In the interview, Dr. Lu stated that "the most difficult part or critical common challenge is how to perform the anastomosis or transection with the surgical stapler, especially in inflammatory or fibrotic tissue" (W.-H. Lu, personal communication, 2022). He identified three issues regarding stapler design based on his experience operating surgical staplers:

1. Slippage between the stapler gripping surface and tissue may lead to malformation of the staple
2. Limitations on the bending angle of the stapler make it difficult for surgeons to accurately apply staples
3. The stapler's large size makes it challenging to maneuver in the limited space available during surgery

Despite these challenges, Dr. Lu also acknowledged the ways in which surgical staplers have improved efficiency and safety in the operating room. He shared that before surgical staplers, surgeons would have to spend 20-30 minutes to create anastomosis by hand sewing the tissue. With a surgical stapler in hand, it takes only a few minutes. The convenience of this medical device is a characteristic that Dr. Lu emphasized and appreciated (W.-H. Lu, personal communication, 2022).

The team also consulted former J&J stapler salesperson, Frank Chen, on what are the most important features promoted when selling surgical staplers. The two key factors Chen described were uniform stapling and tucking in tissue without leakage. If the stapler malfunctions or an emergent issue arises as the stapler clamps and cuts the targeted tissue, there is potential for bleeding damage or leakage to occur. Chen pointed out that leakage rate is a critical issue influenced by the strength of the patient's tissue and performance of the stapler. Furthermore, similarly to Dr. Lu, Chen communicated to the research team that reducing surgery time is an important metric for most medical devices, particularly staplers (F. Chen, personal communication, 2022).

4.3 Patent Search & Visualization Tools

To accomplish the team's objective of applying Boolean grammar to filter and acquire data from patent databases, the team compared various patent databases, search strategies, and

visualization tools. The team utilized three patent databases for archival research: Google Patents, GPSS, and The Lens. After reading through an initial patent provided by Dr. Yeh, the team identified the key components in a patent to accelerate the patent brief creation process. The team established the patent title, abstract, claims, and figures as the primary areas of focus when skimming patents.

The team utilized GPSS and Google Patents in parallel during the initial stages of developing the Boolean search strategy for narrowing the search results to a reasonable number of patents: under 500 patents. For most AND, OR, and NOT search terms, the team applied the keyword filtering to just the patent title, abstract, and claims to focus on the key components of the patents. Several useful search filtering tools the team found on GPSS and Google Patents included the ability to limit to keywords, patent assignees, IPC/CPC codes, and patent filing date.

CEO and founder of SearchRealFast.com, Peter Fenner, introduced the team to an additional patent database, The Lens (P. Fenner, personal communication, 2022). After a brief lesson on the website's useful tools, the team discovered that its search filter parameters were more extensive than the other databases and that the website had unique visualizations of resultant patent data. For example, The Lens allows a user to view a hierarchy of the IPC and CPC classifications as shown in Figure 4.1, making it convenient to find the most relevant code for the search query.

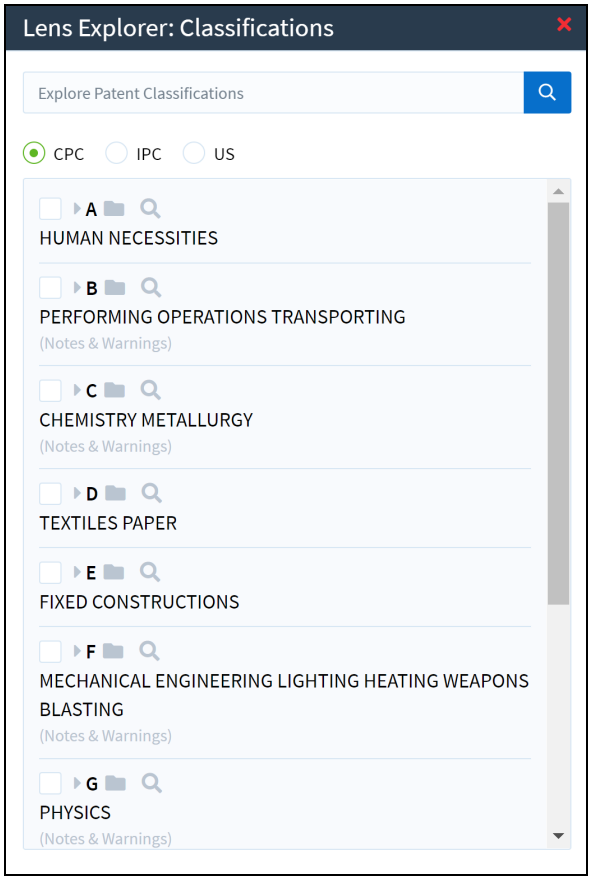


Figure 4.1. CPC, IPC, and US classification explorer. (The Lens, 2022)

With advice from Dr. Yeh, the team formed the final search strategy and determined the primary database for searches would be The Lens. The export tool available on The Lens allowed the team to generate a comma-separated values (CSV) file of the search results with the important fields such as application date, title, abstract, IPC codes, applicants, and owners. The CSV file the export tool generated significantly improved the team's efficiency with gathering the information necessary for the patent briefs, nearly negating the need to search through patent documents for basic information such as the patent's filing date.

After numerous iterations of the search strategy shown in Table 3.1, the team arrived at a final search query, "(title:(surg* AND stapl* AND cart* AND linear* AND fir* NOT

microneedle* NOT circuit*) OR abstract:(surg* AND stapl* AND cart* AND linear* AND fir* NOT microneedle* NOT circuit*) OR claim:(surg* AND stapl* AND cart* AND linear* AND fir* NOT microneedle* NOT circuit*)) AND (applicant.name:ethicon* OR applicant.name:covidien*)", which searches for linear surgical stapler cartridges with attention paid to the firing function. The query also excludes patents with claims relating to microneedles or circuits, as those were common themes seen in patents that Summed Taiwan deemed irrelevant to the project. Combining this query with the filter of the IPC classification for surgical stapler cartridges (A61B2017/0721) yielded a final sum of 185 patents. Summed Taiwan approved this search, allowing for the creation of patent briefs for each of the 185 patents and population of the T-F table.

In addition to exporting patent information for patent briefs, the team recorded various visual aids provided by The Lens for the final patent search. Figure 4.2 displays patent documentation over time for the final search query results. These results show that since 2012, the number of patents filed (applications) and granted for surgical stapler cartridges each year has increased significantly from 6 patents in 2012 to 25 patents in 2020. This increase shows a positive trend in surgical stapler innovation and proves the increased need for patent mapping to display new areas for development.

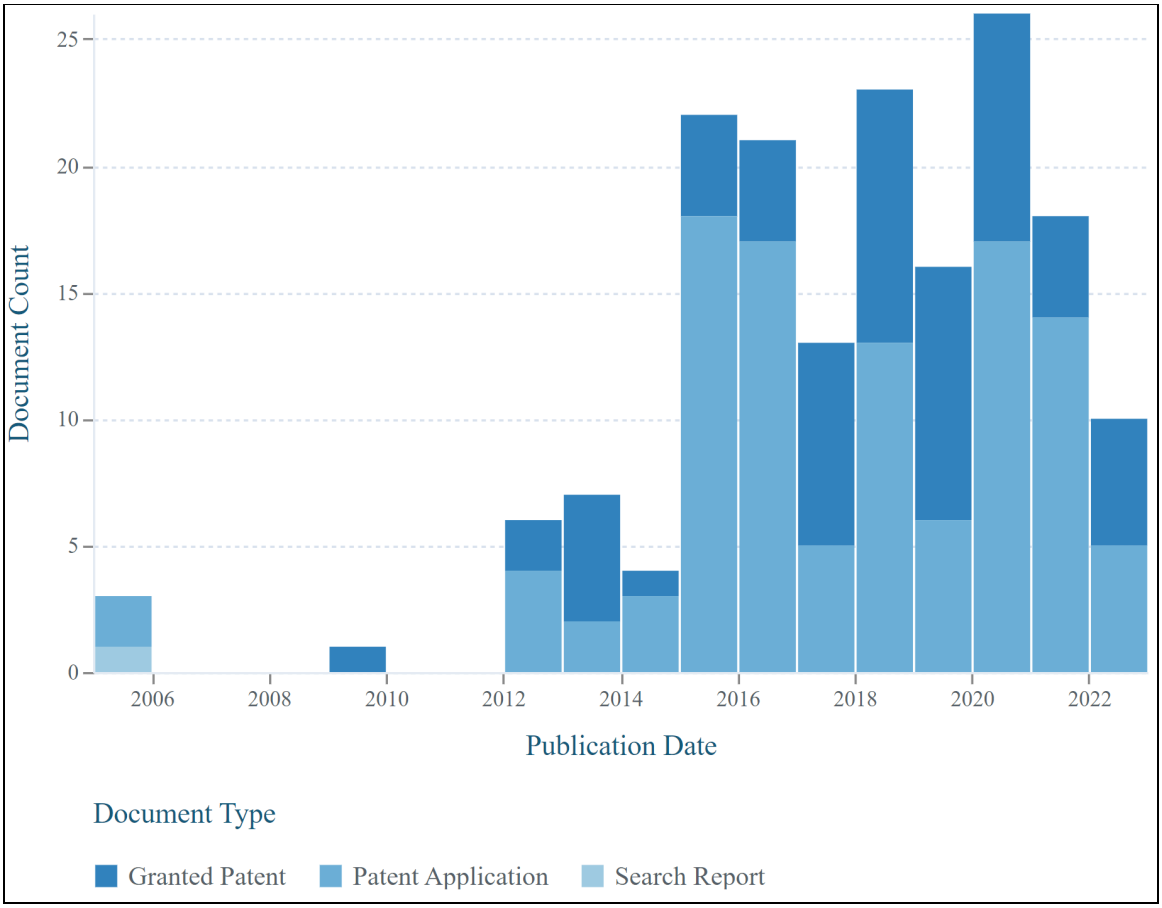


Figure 4.2. Patent documentation over time. (The Lens, 2022)

The Lens also provided a horizontal bar graph of the document type breakdown of the final patent list. Figure 4.3 shows that a majority of the results are patent applications, rather than granted patents with a small number disregarded in the search reports because they were outside the scope of this project.

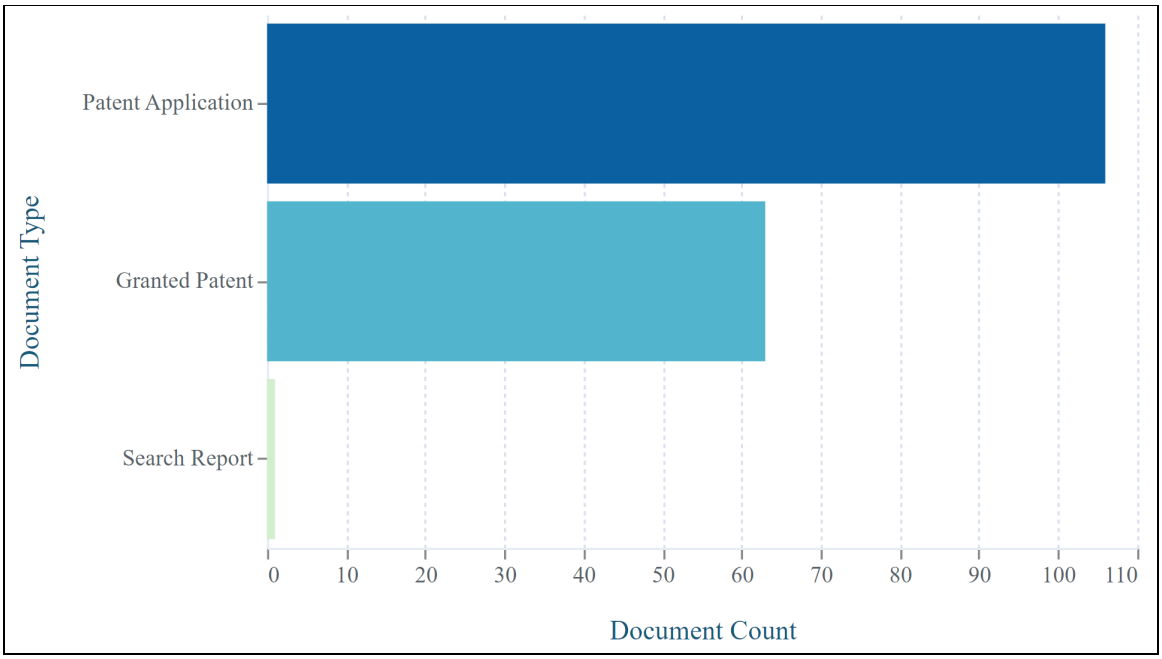


Figure 4.3. Patent documentation by type. (The Lens, 2022)

The distribution of applied and granted patents hints at a larger number of pending patents than active, granted patents, however, the legal status breakdown chart shown in Figure 4.4 disproves this notion. Figure 4.4 shows the majority of patents in the final search are active patents, despite a majority of the patents being applications not yet granted. The ratio of active patents to not granted patents display that the surgical stapler cartridge patent arena is one with a large number of legally enforceable patents, which Summed Taiwan must avoid infringing.

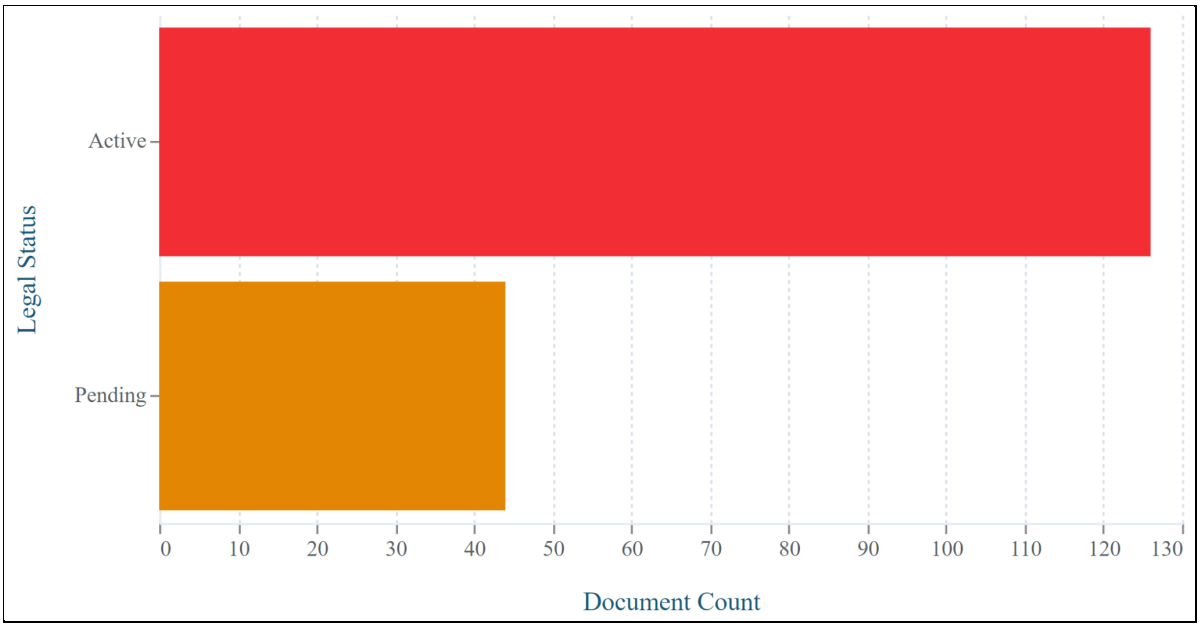


Figure 4.4. Patent documentation by legal status. (The Lens, 2022)

The Lens additionally provided a heat map of the top CPC classification codes for a specified set of search results as shown in Figure 4.5. The CPC classification codes displayed are synonymous with the IPC classifications previously discussed. The heat map shows the chosen classification of A61B2017/07271 as encompassing all of the resultant patents while other related classifications are present. The overlap indicates searched patents have multiple assigned classifications.

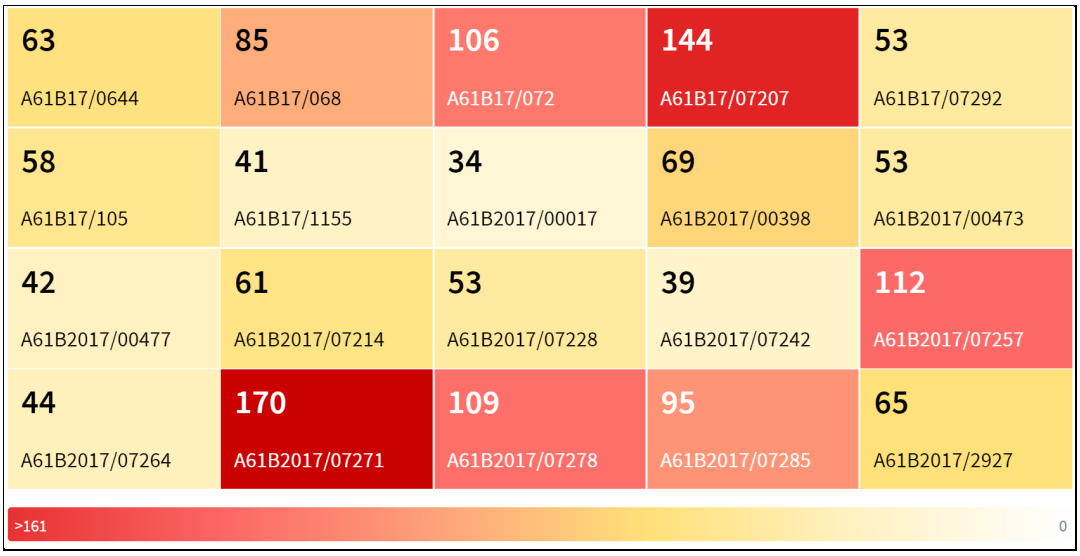


Figure 4.5. Heat map of top CPC classification codes for final patent search. (The Lens, 2022)

Despite the careful efforts of refining the search strategy, duplicate patents in the final results were inevitable due to the fact that The Lens's patent database includes international patents which are often duplicates of those filed in other countries. For example, Covidien may file one patent in the United States, and then subsequently file additional patents in Germany and Japan to provide IP protection in those countries as well. Overall, the team found and removed 125 duplicate or irrelevant patents from the list of patent briefs, bringing the total quantity of patent briefs down to 60. The team read through each patent when creating briefs and based on the claims determined if patents were duplicated from previous applications in other jurisdictions, declined applications, or not relevant to the search terms. This manual filtering was key for the team to create a concise T-F table containing patents relevant to desired technologies and functions.

4.4 T-F Table & Technological Voids

The main deliverable for this project was the completion of a functional T-F table and respective patent briefs for Summed Taiwan to utilize in FTO analysis of the surgical stapler market. Table 4.1 shows the finalized Technology-Function table (patent map) the team developed. The team has each patent ID found in the table linked to its related patent brief described in Figure 4.6. As referenced in the methods, the team organized patent information: ID, title, abstract, and IPC code. Based on the created patent briefs, the sheet organizes each patent into appropriate columns and rows. A link to the created T-F table is in Appendix E.

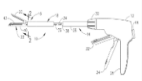
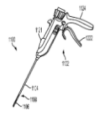
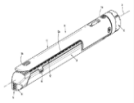
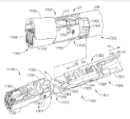
Display Key	Legal Status	Publication Year	Application Number	Application Date	Expired Date	Title	Image	Abstract	Applicants	Owners	Document Type	CPC Classifications	URL	Alternate Identities
US 2020/0038017 A1	Pending	2020	US 201916545(	2019-08-20	2039-08-20	SURGICAL END EFFECTORS WITH STAPLE CARTRIDGES		Method for deforming staples, in which compression is applied when contacting the first inner surface with the end of the first staple leg to bend the end of the first staple leg toward a first side of the base, and deforming the first staple leg such that the end of the first staple leg crosses a mid-line of the staple defined between the first staple leg and the second staple leg.	ETHICON LLC	CILAG GMBH INTERNATIONAL (2021-04-05)	Patent Application	A61B17/0644;;A61	https://lens.org/052-800-781-781-841	
US 10004500 B2	Active	2018	US 201414474(	2014-09-02	2034-09-02	Devices and methods for manually retracting a drive shaft, drive beam, and associated components of a surgical fastening device		Mechanism for manually retracting drive shaft, drive beam, and other components in the event of jamming or misfiring.	ETHICON ENDO SURGERY INC;;ETHICON LLC	CILAG GMBH INTERNATIONAL (2021-04-05);; ETHICON ENDO-SURGERY INC (2014-09-10);; ETHICON LLC (2016-12-30)	Granted Patent	A61B17/0644;;A61	https://lens.org/132-313-406-927-548	US 2016/0058444 A1
US 10736631 B2	Active	2020	US 201816056(	2018-08-07	2038-08-07	End effector with staple cartridge ejector		Staple Ejector assembly that includes an ejector button that is supported on the channel member and engages the angled lower surface of the staple cartridge such that movement of the ejector button from an advanced position to a retracted position.	COVIDIEN LP	MEDTRONIC INTERNATIONAL IP GMBH (2018-10-29);; COVIDIEN LP (2018-11-22);; COVIDIEN PRIVATE LIMITED (2018-06-18);; MEDTRONIC ENGINEERING AND INNOVATION CENTER PRIVATE LIMITED (2018-06-18)	Granted Patent	A61B17/07207;;A6	https://lens.org/122-219-285-234-636	US 2020/0046352 A1, EP 3607894 A1, EP 3607894 B1
US 11213293 B2	Active	2022	US 201615019(	2016-02-09	2036-02-09	Articulatable surgical instruments with single articulation link arrangements		End effector is pivotally coupled to the elongate shaft assembly pivotal travel about an articulation axis with a single articulation driver.	ETHICON ENDO SURGERY LLC;;CILAG GMBH INT	CILAG GMBH INTERNATIONAL (2021-04-05);; ETHICON LLC (2016-12-30)	Granted Patent	A61B17/07207;;A6	https://lens.org/120-428-846-862-922	

Figure 4.6. Section of final patent brief list.

Table 4.1. Technology-Function table for a surgical stapler cartridge.

Legend			Functions									
Active Pending Expired		Technological Void	Insertion			Clamping		Firing			Severing	
		Unrelated T-F	Sizing	Staple Retention	Locating	Compression	Reliability	Reliability	Accuracy	Stapling	Accuracy	Reliability
Technologies	Head	Articulating	US 2021/0275171 A1		US 10603035 B2 US 10413294 B2 US 2021/0401431 A1 US 11213293 B2 US 11207066 B2 EP 3714808 A2 US 9113874 B2		US 2021/0275171 A1		US 2015/0173750 A1		US 10603035 B2	
		Arcuate (Curved)	US 10265069 B2		US 10265069 B2							
		Modular Head	Modular head enabling size reduction for insertion of surgical tool		EP 3718486 A1 US 11241228 B2 US 11207066 B2 US 2020/0253609 A1		US 9113874 B2 EP 3000415 A2	US 2021/0275171 A1				US 2021/0275171 A1
	Cartridge	Spacing Pins							Modified/improved distance between staples to improve staple accuracy and prevent leakage	US 10736631 B2 US 10499911 B2		
		Curved Tip			EP 3673825 A1		Curved cartridge tip to reduce risk of injury by clamping					
		Unique Staples						EP 2907454 B1 US 2017/0119388 A1 US 8220690 B2	Unique staple design for increased firing accuracy	EP 2907454 B1 US 2017/0119388 A1 US 8220690 B2		
		Staple Cavity	US 10499911 B2	EP 3714808 A2 EP 3000415 A2 EP 3892207 A1 EP 3363381 B1	US 10213201 B2	EP 3892207 A1 US 9877721 B2		EP 3363381 B1		US 8220690 B2 WO 2016/049497 A2 EP 3363381 B1		
		Buttress				US 8561873 B2 US 9107667 B2 EP 3673825 A1		EP 3673825 A1 US 8561873 B2 EP 3892207 A1				
		Modular Cartridge	Modular cartridge enabling size reduction for insertion of surgical tool		Modular cartridge to enable ease of locating operating region							
	Anvil	Fixed Anvil				EP 3772338 A2				US 10772632 B2 EP 3772338 A2 US 11051817 B2 WO 2018/165980 A1		
		Adjustable Anvil				US 8393514 B2 EP 3943018 A1			EP 3943018 A1			
	Firing Member	Staple Driver		US 10004500 B2 US 9421014 B2	US 2018/0168607 A1	US 9867613 B2 US 9844374 B2	US 2018/0168607 A1	US 2015/0173750 A1 EP 2984994 B1 US 9775614 B2	EP 2992838 B1	US 9743930 B2 US 2020/0038017 A1 US 2017/0119388 A1 EP 2989997 B1 US 10335151 B2 EP 2891460 B1 EP 2886062 A2		
		Lockout Mechanism			US 8763877 B2			US 2021/0369271 A1		US 2021/0212690 A1		
	Power Source (Motor)				US 11207066 B2	US 10335151 B2		EP 3501415 A2 US 9113874 B2				EP 3501415 A2 US 9113874 B2
	Tissue Thickness Compensator					US 8393514 B2 EP 3943018 A1 US 9295468 B2	US 9295468 B2	US 8393514 B2	US 8393514 B2			
	Knife										US 11224425 B2 AU 2016/200265 B2 US 11266403 B2 CA 2491767 C	US 11224425 B2 AU 2016/200265 B2
	Camera			US 2021/0186498 A1	Multipurpose camera for locating and observing clamping, firing, and severing				WO 2019/123082 A1		Multipurpose camera for locating and observing clamping, firing, and severing	

Above in Table 4.1 is the completed T-F table with patent codes placed in corresponding locations based on their technology(ies) and function(s) found in their claims. The patent codes have three colors: green, amber, and red which correspond to active, pending, and expired patents respectively. The green fill color donotes technological voids.

The table displays a multitude of technological voids, however, the team found that many of these areas do not have a related function and technology. Figure 4.7 displays technological voids in patents corresponding to technologies and functions: Modular cartridge technology and insertion sizing and locating, modular cartridge and clamping reliability, cartridge buttress and clamping reliability, and cartridge curved tip and clamping reliability.

Legend			Functions				
Active Pending Expired		Technological Void	Insertion			Clamping	
		Unrelated T-F	Sizing	Staple Retention	Locating	Compression	Reliability
Technologies	Cartridge	Spacing Pins					
		Curved Tip			EP 3673825 A1		Curved cartridge tip to reduce risk of injury by clamping
		Unique Staples					
		Staple Cavity	US 10499911 B2	EP 3714808 A2 EP 3000415 A2 EP 3892207 A1 EP 3363381 B1	US 10213201 B2	EP 3892207 A1 US 9877721 B2	
		Buttress				US 8561873 B2 US 9107667 B2 EP 3673825 A1	
		Modular Cartridge	Modular cartridge enabling size reduction for insertion of surgical tool		Modular cartridge to enable ease of locating operating region		

Figure 4.7. Sectional view of the T-F table focusing on several technological voids for the surgical stapler cartridge.

When compared to the previous IQP project with Summed Taiwan, the patent map created similarly displays areas where technological voids exist. Due to the success of the previous team, we referenced their work to create an improved table. One difference between the previous IQP's and this year's patent map is the number of patents. This difference in quantity of patents is due to our search strategy, found in the methods, focusing on the specific patents relating to the cartridge as well as limiting the search to patents owned by Covidien and Ethicon. An additional change with our patent map is the increased detail in the technologies and functions allowing for increased clarity of distinct voids.

With the completion of the T-F table the team was able to determine the practicality of patent mapping for uncovering technological voids. With the ability to display technological voids in the surgical stapler market, the table fulfills the preliminary steps in an FTO assessment

and is a valuable resource for Summed Taiwan to reference before seeking the aid of legal professionals.

In addition to the technological voids identified in the T-F table patent map, the team found additional areas for improvement through the interviews conducted with medical device professionals. In an interview with Dr. Lu, he commented on common complaints with current surgical staplers used in hospitals and provided three suggestions for improvement: improve gripping surface holding tissue, increase bending angle, and reduce size of stapler (W.-H. Lu, personal communication, 2022)

In addition to Dr. Lu's suggestions, when asked what issues a client's experience using surgical staplers, Frank Chen mentioned leakage as a common problem that surgeons had when performing operations with surgical staplers (F. Chen, personal communication, 2022). From this the team determined leakage is another problem Summed Taiwan should consider in development.

5.0 Conclusion

This chapter serves to review the major outcomes of the project, discuss the potential design opportunities, and possible areas for future work. The team's final deliverables for Summed Taiwan will be useful tools for navigating the patent landscape as the company moves forward with the R&D of a new surgical stapler.

5.1 Design Recommendations

The team combined feedback from Dr. Lu and the technological voids identified in the T-F table to generate three cartridge-related design recommendations for Summed Taiwan.

1. Curved cartridge tip to reduce risk of injury during clamping of tissue
2. Modular cartridge to assist with minimizing overall size and improving maneuverability of the device during insertion and location of the tissue region
3. Modified or improved distance between staples to improve staple accuracy and prevent leakage

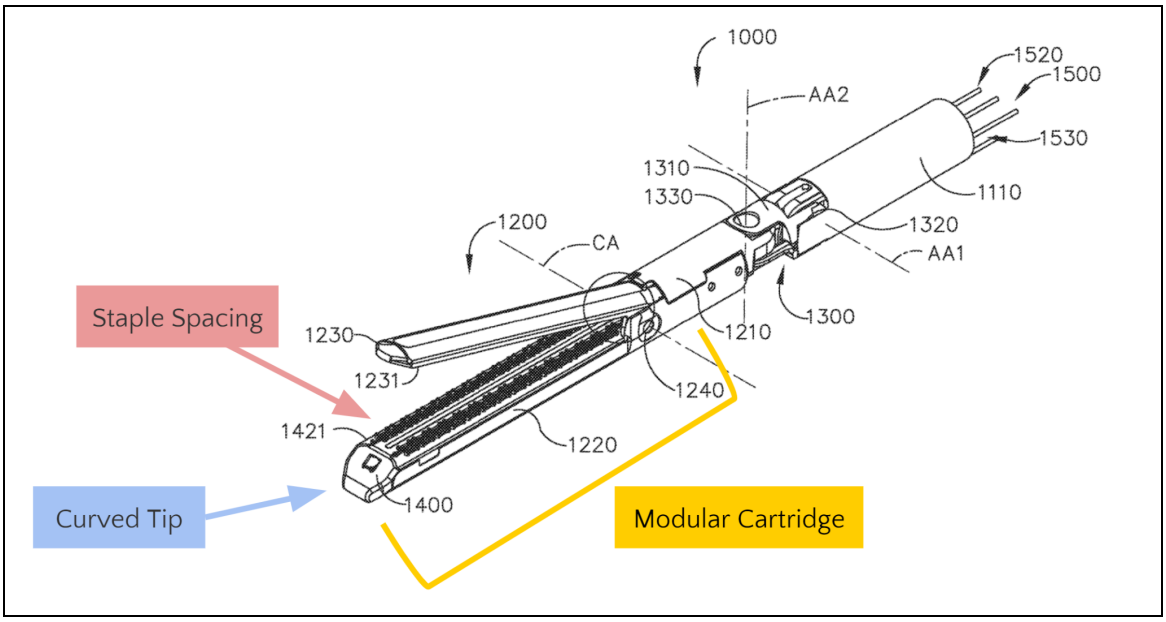


Figure 5.1. Annotated drawing of surgical stapler cartridge design recommendations with base drawing from US20210186498A1. (Boudreaux, C. et al., 2021)

Summed Taiwan is currently in the preliminary stages of conducting R&D for an innovative surgical stapler, and will consider the team's recommendations in determining an initial set of options for cartridge design improvements. The first recommendation shown in Figure 5.1 is the curved cartridge tip, which will address the technological void of tissue clamping reliability and reduce risk of injury during surgery. The second recommendation from the team is to develop a modular cartridge to address Dr. Lu's dissatisfaction with maneuverability of current staplers and the technological void of locating the tissue region during insertion. Finally, the team's last recommendation is to modify the distance between staples, filling the technological void of improving staple accuracy and addressing Mr. Chen's concerns with leakage prevention.

5.3 Limitations & Future Work

The team faced various challenges and encountered several limitations throughout this project that may be circumnavigated in future projects. The project's short seven week timeline made creating the appropriate search strategy and the full set of deliverables a challenge for the team. Nevertheless, the team recorded thorough documentation of the patent databases, visualization tools, and search strategy development process, all of which will be a key resource for accelerating patent archival research in future projects.

As mentioned in Section 3.3, the timeline and team's limited legal knowledge also hindered the team's ability to conduct a full-fledged FTO analysis. While archival research of IP policies was important in preparing to make a patent map, future projects should aim to interview

patent attorneys to gain a deeper understanding of how a patent map is typically utilized in an FTO analysis. Furthermore, future teams should be aware that a patent map is only a small, preliminary component of a complicated level of legal analysis beyond the scope of this project.

The medical device industry is particularly complex, posing issues for both manufacturers and regulators. Given the rapid pace of technological advancement in the global medical device sector, marketing and supply chain strategy is a critical element. Due to the excessively long licensing process of IP regulations, certain devices may not be available to medical professionals for treating patients until later in the product life cycle. Delaying new and developing treatments from reaching the market, the hospitals, doctors, and their patients' well-being may suffer as a consequence.

Based on the team’s research, the global medical device business is entering a new era of opportunities to provide even more efficient and higher-quality products to the public and healthcare professionals. Taiwan is an appealing venue for global medical device companies to conduct research if it can marshal the required resources and demonstrate its ability to be a major player in the market. The rate of technical progress in medical devices has accelerated in recent years, resulting in potential for achieving future health advantages. New opportunities will arise from both established corporations and startups, while strong collaboration between suppliers and regulators will be required to ensure that these new procedures and technology are integrated into the existing healthcare system. Taiwan can continue to provide universal national healthcare that is not only financially viable, but also makes new and innovative technologies available to Taiwanese doctors and patients in need of the most effective treatments on a regular basis. The team provided assistance to Summed Taiwan, allowing them to be a part of an industry that is

continually working to improve health circumstances, including improved longevity and quality of life.

Bibliography

Abbas, A., Zhang, L., & Khan, S. (2014). A literature review on the state-of-the-art in patent analysis. *World Patent Information*, *37*, 3–13. https://doi.org/10.1016/j.wpi.2013.12.006

Berg, B. L., & Lune, H. (2017). *Qualitative research methods for the social sciences* (Ninth edition). Pearson.

Briggs, A. R. (2004). *Patient orientation and freedom to operate in the management of technology* [Massachusetts Institute of Technology, Sloan School of Management]. https://dspace.mit.edu/handle/1721.1/28684

Chekan, E., & Whelan, R. L. (2014). Surgical stapling device-tissue interactions: What surgeons need to know to improve patient outcomes. *Medical Devices (Auckland, N.Z.)*, *7*, 305–318. https://doi.org/10.2147/MDER.S67338

Chen, F. (2022). *Interview* [Personal communication].

Cho, T.-S., & Shih, H.-Y. (2011). Patent citation network analysis of core and emerging technologies in Taiwan: 1997–2008. *Scientometrics*, *89*(3), 795–811. https://doi.org/10.1007/s11192-011-0457-z

Espacenet. (2019). *Classification search*. Espacenet Patent Search. https://worldwide.espacenet.com/classification?locale=en_EP#!/CPC=A61B2017/07271

Farre-Mensa, J., Hegde, D., & Ljungqvist, A. (2020). What Is a Patent Worth? Evidence from the U.S. Patent "Lottery." *The Journal of Finance*, *75*(2), 639–682. https://doi.org/10.1111/jofi.12867

Fenner, P. (2022). *Interview* [Personal communication].

Foote, S. B. (1991). The Impact of Public Policy on Medical Device Innovation: A Case of Polyintervention. In *The Changing Economics of Medical Technology*. Institute of Medicine (US) Committee on Technological Innovation in Medicine.

Frederick E. Shelton, IV, Michael Earl Setser, & Brian J. Hemmelgarn. (2006). *Surgical stapling instrument having separate distinct closing and firing systems* (Patent No. US7000818B2).

Frietsch, R., Neuhäusler, P., Jung, T., & Van Looy, B. (2014). Patent indicators for macroeconomic growth—The value of patents estimated by export volume. *Technovation*, *34*(9), 546–558. https://doi.org/10.1016/j.technovation.2014.05.007

Gaidry, A. D., Tremblay, L., Nakayama, D., & Ignacio, R. C. (2019). The History of Surgical Staplers: A Combination of Hungarian, Russian, and American Innovation. *The American Surgeon*, *85*(6), 563–566.

Gold, E. R., Kaplan, W., Orbinski, J., Harland-Logan, S., & N-Marandi, S. (2010). Are Patents Impeding Medical Care and Innovation? *PLoS Medicine*, *7*(1), e1000208. https://doi.org/10.1371/journal.pmed.1000208

Huang, J., & Chang, P. (2010). Selling patents to companies in Taiwan. *Asian Journal of Technology Innovation*, *18*(2), 1–19. https://doi.org/10.1080/19761597.2010.9668690

Keiller, T. (2022). *Interview* [Personal communication].

Lee, S., Yoon, B., & Park, Y. (2009). An approach to discovering new technology opportunities: Keyword-based patent map approach. *Technovation*, *29*(6–7), 481–497. https://doi.org/10.1016/j.technovation.2008.10.006

Lee, Y.-G. (2008). Patent licensability and life: A study of U.S. patents registered by South Korean public research institutes. *Scientometrics*, *75*(3), 463–471. https://doi.org/10.1007/s11192-007-1879-5

Leydesdorff, L., Kushnir, D., & Rafols, I. (2014). Interactive overlay maps for US patent (USPTO) data based on International Patent Classification (IPC). *Scientometrics*, *98*(3), 1583–1599. https://doi.org/10.1007/s11192-012-0923-2

Lu, W.-H. (2022). *Interview* [Personal communication].

Mayfield, D. L. (2016). Medical Patents and How New Instruments or Medications Might Be Patented. *Missouri Medicine*, *113*(6), 456–462.

Noh, H., Jo, Y., & Lee, S. (2015). Keyword selection and processing strategy for applying text mining to patent analysis. *Expert Systems with Applications*, *42*(9), 4348–4360. https://doi.org/10.1016/j.eswa.2015.01.050

Oldham, P., & Cutter, A. M. (2006). Mapping Global Status and Trends in Patent Activity for Biological and Genetic Material. *Genomics, Society and Policy*, *2*(2), 62. https://doi.org/10.1186/1746-5354-2-2-62

Park, H., Yoon, J., & Kim, K. (2012). Identifying patent infringement using SAO based semantic technological similarities. *Scientometrics*, *90*(2), 515–529. https://doi.org/10.1007/s11192-011-0522-7

Park, I., & Yoon, B. (2014). A semantic analysis approach for identifying patent infringement based on a product–patent map. *Technology Analysis & Strategic Management*, *26*(8), 855–874. https://doi.org/10.1080/09537325.2014.909926

Polizzotto, L. (2022). *Interview* [Personal communication].

Summed Taiwan. (2022). *About Summed*. https://www.summedtw.com/%E9%97%9C%E6%96%BC%E8%8B%A1%E6%A8%82?lang=en

Tseng, Y.-H., Lin, C.-J., & Lin, Y.-I. (2007). Text mining techniques for patent analysis. *Information Processing & Management*, *43*(5), 1216–1247. https://doi.org/10.1016/j.ipm.2006.11.011

U.S. Food and Drug Administration. (2019a). *Class 1 Device Recall ECHELON FLEX Powered Plus ENDOPATH 60mm Stapler* [Recall]. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?id=176698

U.S. Food and Drug Administration. (2019b). *Safe Use of Surgical Staplers and Staples – Letter to Health Care Providers*. https://www.fda.gov/medical-devices/letters-health-care-providers/safe-use-surgical-staplers-and-staples-letter-health-care-providers

U.S. Food and Drug Administration. (2021a). *FDA Issues Final Order and Guidance on Surgical Staplers and Staples for Internal Use*. https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/surgical-staplers-and-staples

U.S. Food and Drug Administration. (2021b). *Surgical Staplers and Staples*. https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/surgical-staplers-and-staples

U.S. Food and Drug Administration. (2022). *Medical Device Recalls*. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?start_search=1&event_

id=&productdescriptiontxt=staple&productcode=&IVDProducts=&rootCauseText=&recallstatus=&centerclassificationtypetext=&recallnumber=&postdatefrom=&postdateto=&productshortreasontxt=&firmlegalnam=&PMA_510K_Num=&pnumber=&knumber=&PAGENUM=500

Wang, M.-Y., Lin, J.-H., & Lo, H.-C. (2012). Influential Factors of the Commercialization of Academic Patents: The Taiwan Experience. *2012 Proceedings of PICMET '12: Technology Management for Emerging Technologies*, 1830–1836.

Wong, J. (2016). The Developmental State and Taiwan. In G. Schubert (Ed.), *Routledge Handbook of Contemporary Taiwan* (pp. 201–217). Routledge.

Xu, H., Chen, Y., & Longo, A. (2021). *Proposal for an Innovative Disposable Endoscope in Partnership with Summed Taiwan in 2021*. Worcester Polytechnic Institute.

Yang, C.-H. (2008). Effects of Strengthening Intellectual Property Rights in Newly Industrialized Economies: Evidence From Taiwan's 1994 Patent Reform. *Contemporary Economic Policy*, *26*(2), 259–275. https://doi.org/10.1111/j.1465-7287.2007.00095.x

Yock, P. G., Zenios, S., Makower, J., Brinton, T. J., Kumar, U. N., & Watkins, F. T. J. (Eds.). (2015). *Biodesign: The process of innovating medical technologies* (Second edition). Cambridge University Press.

Yoon, J., Park, H., & Kim, K. (2013). Identifying technological competition trends for R&D planning using dynamic patent maps: SAO-based content analysis. *Scientometrics*, *94*(1), 313–331. https://doi.org/10.1007/s11192-012-0830-6

Zheng, Y. (2022). *Interview* [Personal communication].

Appendices

Appendix A: Medical Device Expert Interview Guide

Questions

1. Could you share a brief description of your work history in the medical field and entrepreneurship up to the present?
2. Could you speak on your experience with identifying unmet needs in the medical device market?
    a. Would FDA recalls be a source of motivation?
    b. What are some other sources of recalls?
3. What has been your experience with intellectual property regulations when developing new medical devices?
4. What are some common issues you have run into with IP regulations and patents?
5. As our team is working with a medical device investment company in Taiwan, we are investigating the international aspect of IP and government influence on foreign markets.
    a. What government agencies or regulatory bodies have power to conduct recalls in other countries? (e.g. FDA recall in Taiwan)
6. Have you had any frustrations or challenges when working with FDA regulations, FTO, and when determining patentability?
    a. What are some consequences of medical device reclassification?

Appendix B: Biomedical Professor Interview Guide

Questions

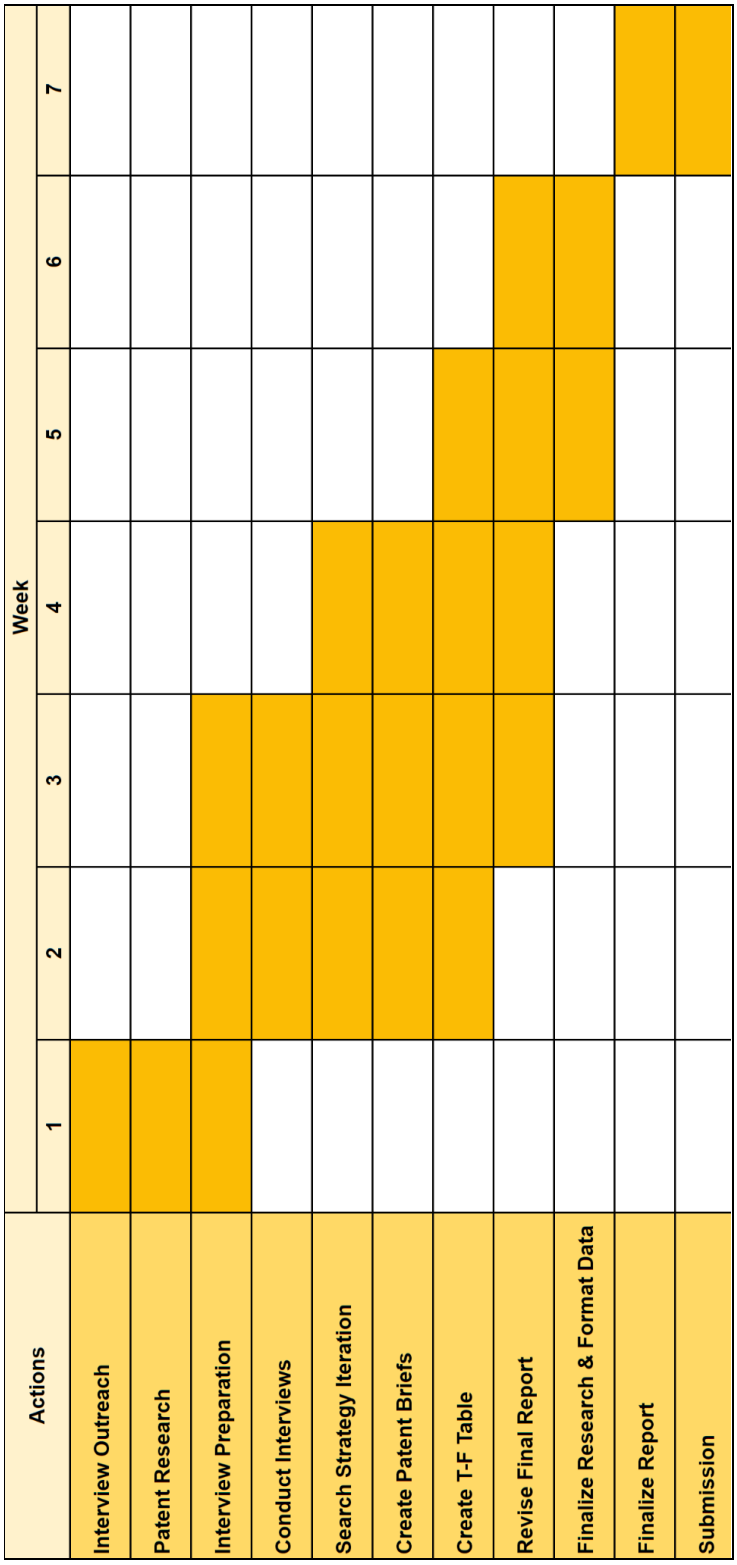
1. What title or position do you hold at your academic institution?
2. Could you describe what type of research you and your group focus on?
3. How often do you use or interact with surgical staplers in your research area?
4. What are the key features of surgical staplers?
5. Are there any areas of improvements you believe should be investigated further in surgical stapler research?
6. What has been your experience with intellectual property regulations when developing new medical devices with startups?
7. What are some common problems you have run into with IP regulations and patents?
8. Have you encountered patent maps at all while working with startups?
9. In your experience, what role have FTO analyses played in the development of medical devices?
10. What are some characteristics of a successful startup attempting to improve an existing type of device?
11. Have you had any frustrations or challenges when working with FTO and determining patentability?
12. Could you elaborate on the Boolean strategy?
13. Do you have any additional contacts that we can reach out to, either with experience with surgical staplers or IP?

Appendix C: Legal Expert Interview Guide

Questions

1. Could you give us a brief description of your background and experience in intellectual property?
2. What has been your experience with working with research labs or startups developing new medical devices?
3. What are some common problems you have run into with IP regulations and patents?
4. What is the role of FTO in forming patents?
5. Have you had any common frustrations or challenges when working with FTO and determining patentability?
6. Have you encountered patent maps for FTO analysis in your current role at work?
    a. If so, was the map useful for your team?
7. Do you have any final advice for our team as we research existing patents?

Appendix D: Timeline



Appendix E: T-F Table Link

https://docs.google.com/spreadsheets/d/1YESrGgW3Sf7vCcKRZteAmhMYKyv8YdMLcYAxrhIxJZM/edit?usp=sharing