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Evaluating the Commercial Pathway of Emerging Cardiac Patch Technology

A Major Qualifying Project
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Abstract

The overall objective of this research was to evaluate the commercial pathway of emerging cardiac patch technology. Our review of the state of the art indicated that the current cardiovascular patch market would benefit from a cardiac patch that promotes regeneration of myocardial tissue as well as prompts both mechanical and electrical properties. The approach presented relies on the decomposition of the functional elements of determining the commercial pathway, which includes (1) determining the customer applicability for the cardiac patch user, (2) evaluating the current cardiac patch competitive landscape, and (3) determining the best go-to-market strategy for generating income. Methods used included: performing external research on the biomedical engineering device market as well as conducting interviews with professionals in the industry. The results gathered from our research show the value proposition of the cardiac patch technology in the market. The information and research gathered allowed the project team to draw a conclusion on the commercial pathway of the cardiac patch, and determine the business model that best fits the market.

Authorship

This project was completed through a collaborative effort between project team members: Gabrielle France, Rachael Lanni, as well as Morgan Maiola. Each group member had equal contribution to all chapters of the paper, working together to write, edit, and discuss all sections.

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Finally, we would like to thank Professor Pins' previous PhD student and current PhD student for providing financial and other information regarding the creation of a cardiac patch.

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Chapter 1: Introduction

Nearly 800,000 Americans have a heart attack every year, which is equal to one attack every 40 seconds (Benjamin, 2017). Coronary artery disease is the leading cause of myocardial infarctions, or heart attacks, as high plaque buildup in arteries can lead to a blockage or rupture in the heart. Heart attacks increase a person's chance of heart failure, abnormal heart rhythms, sudden cardiac arrest, damaged organ function throughout the body, or even death ("Understanding Heart Attack," 2017). Despite the fact that heart attacks have become increasingly common, there remain little treatment options for those afflicted. Cardiac transplantation surgery is one treatment, but has a 99% mortality rate (Pins, Personal Communication, 2017).

In recent years, cardiac patches have gained popularity by attempting to replace damaged or scarred heart tissue. The structure of a cardiac patch combines cell therapies and bioengineered scaffolding to try to encourage myocardial tissue regeneration. However, current cardiac patches on the market are deeply limited in functional ability, as most are made of synthetic materials that lack the mechanical and electrical properties of the heart. Therefore, there remains a significant unmet need to develop a cardiac patch with integrated contractile properties for proper myocardial regeneration (Pins, Personal Communication, 2017).

Professors George Pins and Glenn Gaudette of Worcester Polytechnic Institute have developed a composite cardiac patch made up of layers of microthread-based composite scaffolds and rat cells. The goal of the cardiac patch as bioengineered myocardium is to replace a piece of damaged heart tissue with a patch that has the same properties as real cardiac tissue. With strong progress in the development of the cardiac patch, this project, in conjunction with

the WPI Foisie Business School and Biomedical Engineering Department, sought the best method for commercializing this technology.

1.1 Problem Statement

The overall problem that this Major Qualifying Project addressed was evaluating the commercial pathway of emerging cardiac patch technology developed at WPI.

1.2 Project Objectives

The project team sought to complete three main objectives, namely,

1. Determining customer applicability for the cardiac patch user
2. Evaluating the current cardiac patch market
3. Determining the best go-to-market strategy for generating income

Each of these objectives and overall goal were summarized using Axiomatic Design, an engineering design tool, outlined in Chapter 2.

1.3 Project Scope and Deliverables

The focus of this MQP was to evaluate the commercial pathway of emerging cardiac patch technology developed on-campus at WPI. It is important to note that the cardiac patch was still early in its development stage at the time of this MQP. As the biomedical engineering team continues with its development, clinical trials, and gaining FDA approval, the best commercialization route may change in order to best fit the needs of the product and team. This project analyzed customer need, the cardiac patch market, and three business model routes in order to determine whether the cardiac patch was worth commercializing. The deliverables for this MQP included:

- An analysis of the current cardiac patch market and potential demand

- A comparison of licensing, acquisition, and start-up commercialization options
- Recommended geographic locations for initial market entry
- Recommended best go-to-market route of commercialization at this stage of development
- A cost-benefit analysis for use throughout the future development process
- An Excel sheet with detailed financials
- A situation analysis using traditional business tools including:
 - o SWOT Analysis: Strengths, weaknesses, opportunities, and threats
 - o 5 C's Analysis: Company, customers, competitors, collaborators, and context

1.4 Project Timeline

The MQP began on August 24th, 2017 and ended on March 2nd, 2018. The Gantt chart in Appendix E shows a detailed outline of each of the project steps throughout the 21-week timeline.

Chapter 2: Methodology

The methodology was broken down into categories that are related to the project timeline.

- 1) Week 1-7: Determining the Problem
 - a) Axiomatic Design and Acclaro
- 2) Week 8-14: Information Acquisition
 - a) Research
 - i) Medical literature on various types of infarcts, medical devices
 - ii) Research on intellectual property and patents for medical devices
 - b) Contacts
 - i) Medical device companies
 - ii) Medical device consulting firms
 - iii) WPI professors, staff, alumni
- 3) Week 15-21: Analyses
 - a) Cost-Benefit Analysis
 - b) Results and Recommendations

The information gathered from performing these methods was used to further determine the marketability of the cardiac patch. In-depth analyses of this data were conducted to use this information to create educated recommendations for the cardiac patch development team.

2.1 Week 1-7 Approach: Determining the Problem

The approach taken for the beginning weeks of the project was broken down into the following steps:

1. Master the functions of Acclaro and Axiomatic Design
2. Determine the problem that needs to be solved

3. Research potential competitors of the cardiac patch
4. Acquire information on industry standards for commercialization

Axiomatic design was developed by Nam Suh as an engineering design tool, to help engineers pick out a “good” design structure in the most efficient manner possible. A “good” design is one that solves a problem in the simplest and easiest way. Axiomatic design teaches users how to create the most appropriate system solutions and improvements for the most effective outcomes. Essentially, axiomatic design facilitates a better, faster, and cheaper approach to engineering design as a whole (Brown, 2013). The design technique has two guiding axioms:

Axiom 1: Maximize independence

Axiom 2: Minimize information content

Maximizing the independence of functional requirements for a design allows the engineer to change design elements without affecting the other design requirements. Minimizing the information content provides for a robust design with the highest probability of successfully fulfilling the goals of the design. Together, these two axioms allow for objective evaluations of the various possible designs at hand.

Functional requirements are those pieces of the design required to complete the problem at hand. The top-level functional requirement, also known as FR0, is the overarching goal of the design and project. Each of the project’s three main objectives are additional functional requirements, displayed as subsets or children of FR0. These subset children should add up together to equal the main functional requirement, FR0. For example, if a design requires three functional requirements to complete FR0, then the following must be true:

$$FR0 = FR1 + FR2 + FR3$$

In addition to functional requirements, axiomatic design requires that there also be design parameters. Each functional requirement is paired with a single design parameter. These design parameters outline the action taken to complete the requirements, using systems or tools.

Using the software application Acclaro, the project team was able to decompose the MQP problem using axiomatic design (Axiomatic Design Solutions, Inc., 2012). Figure 1 displays the functional requirements and corresponding design parameters for this MQP.

#	[FR] Functional Requirements	[DP] Design Parameters
0	Evaluate the commercial pathway of emerging cardiac patch technology	System to evaluate the commercial pathway of emerging cardiac patch technology
1	Determine customer applicability for the cardiac patch user	Method to determine customer applicability for the cardiac patch user
2	Evaluate the current cardiac patch market and competitive landscape	Method to evaluate the current cardiac patch competitive landscape
3	Determine the best go-to-market strategy for generating income	Method to determine the best go-to-market strategy for generating income

Figure 1: Acclaro Axiomatic Design Decomposition

Axiom two is satisfied with the above functional requirements being collectively exhaustive. In other words, the team and advisors agreed that these functional requirements exhaust all those required to evaluate the commercial pathway of the emerging cardiac patch technology. Analyzing customer applicability, evaluating the current cardiac patch market and competitors, and comparing go-to-market strategies addressed the project team's goal. Axiom one is satisfied with the above functional requirements being mutually exclusive. This is confirmed by the independence matrix produced by Acclaro during the FR-DP decomposition. Since the matrix indicates that all FR-DP pairs are uncoupled, the team is able to change one design requirement without affecting the others. This also signals that the requirements were in the correct order of which they must be completed for the successful completion of FR0, as indicated by the coupling matrix in Table 1.

	<i>DP0</i>	<i>DP1</i>	<i>DP2</i>	<i>DP3</i>
<i>FR0</i>	X	O	O	O
<i>FR1</i>	O	X	O	O
<i>FR2</i>	O	O	X	O
<i>FR3</i>	O	O	O	X

Table 1: Top Level Design Coupling Matrix

2.2 Week 8-14 Approach: Information Acquisition

The acquisition of information and data took a number of forms, namely:

1. Cold calls to medical device companies
2. Contacting medical device consulting firms
3. Networking with various WPI professors and staff

The team's first method to gain information on medical device commercialization was to reach out to medical device companies directly. The calls returned resulted in direction through the company's website, product profiles, and the general consensus that each company had its own method for commercializing new products. As a second method, the team then reached out to medical device consulting firms, since the team's position between companies and the patch developers was much like that of a medical device consulting firm. Inquiries with a number of commercialization firms across the country led to various educational videos and lectures on commercializing medical devices. The team discovered, through this outlet, the three major go-to-market commercialization routes of licensing, acquiring, and building a start-up.

The team's third method of information acquisition consisted of reaching out to contacts within the WPI network. Professor Pins' past and present biomedical engineering PhD students provided details on the technological aspects and cost structure of the cardiac patch materials. The team also reached out to Yael Schwartz, WPI's entrepreneur-in-residence, Attorney Robert Lombardi, adjunct teaching professor at WPI, and Laura Robinson, WPI's lead research librarian for insight within their respective professional backgrounds.

Additionally, personal connections through LinkedIn led the team to further resources and contacts, including:

- Commercialization experts (of any product)
- Commercialization experts (of medical devices)
- Business development of laboratories
- Product development experts (of medical devices)
- Law firms
- WPI alumni in the medical device industry
- Online research

Any information obtained from the stated sources is referred to using in-text citations.

2.3 Week 15-21 Approach: Analyses

With the problem defined and information acquired, the project team determined benefits and costs of commercialization, as well as accomplished the goal of recommending the best route of commercialization to the cardiac patch development team in the final seven weeks of the project. In order to do so, the team:

- Analyzed medical technology Harvard Business School cases
- Determined value-added benefits of the patch

- Calculated patch material and indirect costs
- Recommended the best go-to-market route
- Established next steps for the cardiac patch development team

The project team first analyzed several Harvard Business School cases, including the case titled, “Tengion: Bringing Regenerative Medicine to Life,” which outlined the situation of competing products within a single company pipeline (Ofek, 2014). With these cases, the project team was able to establish the foundation for calculating possible benefits from the commercialization of the cardiac patch. The two calculations used to measure added value from new medical devices included 1) savings from reduced post-operative complications and 2) increase in patients' quality of life. The project team outlined how these calculations can be used by the biomedical development team in order to measure the value of the cardiac patch.

The project team also allocated indirect costs on a per patch basis. Indirect costs included the total cost of the regulatory process from the FDA for a Class III medical device and the cost of securing proper intellectual property. The team also reached out to UMASS Medical School's Office of Technology Transfer for guidance on forming recommendations and next steps for the commercialization of the cardiac patch.

With the methods outlined above, the project team recommended the best go-to-market route for commercialization of the cardiac patch at this stage of development and provided Professor Pins and the development team with next steps for commercialization.

Chapter 3: Results

The project team concluded that the cardiac patch could successfully be commercialized given the following criteria:

1. There exists an unmet customer need.
2. There exists a market for the product, with healthy competition and positive growth.
3. There exists three medical technology business models for profiting from the commercialization process of the cardiac patch.

The following sections provide more detail on each of the three criteria above, including a comparison of the advantages and disadvantages of licensing, acquisition, and start-up medical technology business models for commercialization of the cardiac patch. This chapter also outlines the cost of patch materials and indirect costs, such as FDA approval and securing intellectual property rights, as well as the value-added benefits to patients and the cardiac patch development team through successful commercialization.

3.1 Value Proposition

3.1.1 Unmet Customer Need

Every year, 790,000 Americans suffer from a myocardial infarct, more commonly known as a heart attack. Of those nearly 800,000 people, 73% experience their first heart attack, while 27% have a repeat occurrence (Benjamin, 2017). With 86% surviving, this leaves nearly 680,000 patients now seeking regular cardiac medical care (Mozaffarian, 2017). These patients seeking regular cardiac medical care, after surviving a heart attack, would make up the potential market demand of those who could benefit from a cardiac patch.

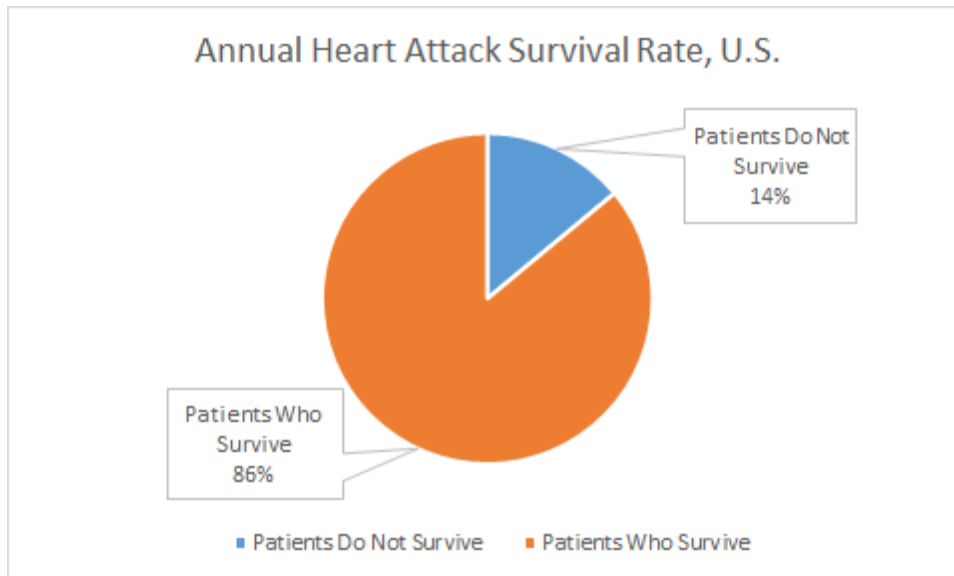


Figure 2: Annual Heart Attack Survival Rate, U.S.

Damaged myocardium is one the leading causes of heart failure in patients, although there are few options for fixing or replacing the damaged heart tissue (Ertl, 2005). One treatment for patients whose heart failure has become serious since their heart attack is that of a heart transplant. About 2,000 heart transplants are performed each year in the United States, but the treatment greatly lacks available donors who are able to provide hearts. Additionally, the median survival rate of patients receiving a heart transplant is only about nine years (Everly, 2008).

Cardiac patches provide a treatment option for those patients suffering from a heart attack, to slow or avoid heart failure. Following the heart attack, a patient can receive a cardiac patch which works to replace the damaged heart tissue and restore regular cardiac tissue properties and functions. The cardiac patch avoids the need for a heart transplant. Therefore, there is still a clear, unmet need for improved cardiac patches.

3.1.2 Market Evaluation

The markets for heart attack treatments and cardiac patches both have positive growth outlooks over the next five years. As of 2016, the market for myocardial infarction treatment was valued at more than \$1.2 billion. That number is expected to grow annually at a rate of just over 6% to \$1.7 billion by 2022, according to a recent study conducted by Zion Market Research (Zion Market Research, 2017). Specifically, the market for cardiac and soft tissue repair patches, valued at \$2.5 billion in 2014, is set to grow at an annual rate of 111% to \$5.8 billion by 2022, according to a study by Grand View Research (Grand View Research, 2016).

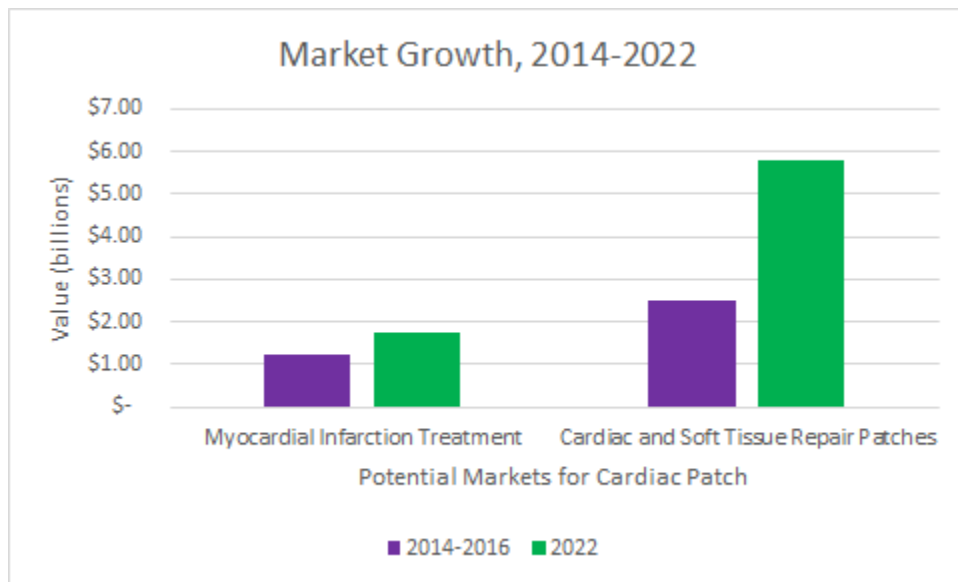


Figure 3: Projected Growth of Markets for the Cardiac Patch

The United States is expected to be one of the fastest growing regional markets between 2012 and 2022, due to the developed healthcare infrastructure. Additionally, there are high awareness levels about the availability of new technology and solutions invented to solve the pre-existing coronary artery disease problem. Thus, in this region, there is a higher usage of cardiac patches, creating a market with healthy competition and room to compete.

3.2 Medtech Business Model Comparisons

Each of the three go-to-market business models including licensing, acquisition, and start-ups, offers unique advantages and some disadvantages, pertaining to profiting from the commercialization of the cardiac patch.

3.2.1 Licensing

Licensing is a method of commercialization which grants another business or entity, termed the “licensee,” rights to use the product or associated technology from the intellectual property of another, termed the “licensor.” The licensor can license certain parts of their intellectual property, limiting the licensee’s use to one specific industry, in order to license to additional entities as well. Another option for the licensor is to license all of their intellectual property in its entirety, in order to allow the licensee to manufacture and sell a prototype of their developed product. In either instance, the licensor keeps ownership of their intellectual property. All terms of a licensing deal are outlined in a contract negotiated by the licensor and licensee.

Licensing has many advantages for those inventors looking to commercialize their ideas, intellectual property, or prototypes. According to Cayenne Consulting, the most notable advantage is that of the financial risk that is mitigated from licensing. The inventor is not responsible for funding, manufacturing costs, or other risks and costs associated with running a business (Hirai, 2001). Each of these is left to the discretion and responsibility of the licensee. Without the need for running one’s own company, the inventor has time to continue researching and essentially "makes money while they sleep" by collecting royalties of up to 5%. In the case of the cardiac patch, another advantage is that of support from a university setting, including the associated Office of Technology Transfer (Davidov, 2013). This office is usually responsible for negotiating contract and licensing terms with inventions from the university campus. A UMASS

Medical, Worcester licensing officer notes that this advantage allows the inventor to decide themselves how involved they become with the legal and negotiating matters of the process (Dr. Rawat, Personal Communication, January 30, 2018).

The largest disadvantage of licensing is that of increased control given up to the licensee. Since the licensee is potentially responsible for use of the intellectual property, manufacturing the product, and making sales, the licensor depends on the licensee for proper usage of their invention. As Dr. Rawat described, “the last thing an inventor wants is for a licensee to simply shelf their idea or product” (Personal Communication, January 30, 2018). In addition, licensing fees and royalty payments have a smaller upside potential for generated income to the inventor. This is true because since the licensee is taking on the most risk, they will likely see more reward than that of the licensor.

3.2.2 Acquisition

Acquisition is another commercialization method in which larger, well-established companies look to acquire single products that are backed by very strong intellectual property positions. Medical device consultants confirm that acquisitions most successfully occur with products that are synergistic to a company’s overall strategy and can compete in “hot” markets at the time (Wodlinger, 2018). Usually a product has already been developed, granted FDA approval, and reached some level of sales for acquisition interests to be triggered. However, one-sixth of medtech acquisitions do still occur when a company is pre-revenue (Hirsch, 2013). With high upside potential for generating income and increased control over the product trajectory, the acquisition model is promising for further developed ideas (Wodlinger, 2018).

The acquisition business model for commercialization includes a number of advantages for the inventor. The monetary benefit is the most pronounced with a very large upside potential

for generating income and making a large sum of money at once. Planning for an acquisition also allows an inventor to take control of their idea or intellectual property and bring it to the market as they see fit. In other words, control is in the owner's hands throughout the entire process. This changes only when the product is actually acquired, and then the company decides the owner's ongoing role (Wodlinger, 2018).

Disadvantages of an acquisition-based commercialization model are mainly focused around the significant time, capital requirements, and risks that are necessary before benefits are acknowledged. Only 25% of medtech acquisitions occur within six years of a company starting out, while most require millions of dollars in venture capital and revenue before being acquired. For example, OptiMedica raised over \$100 million in venture capital, before being acquired by Abbott. Similarly, Salient Surgical had to raise nearly \$130 million in venture capital and produced over \$100 million in annual revenues before being acquired by Medtronic (Hirsch, 2013). The inventor also has the added responsibility of managing normal business functions such as manufacturing and sales, as well as any further development and FDA safety testing as the product is sold. Once an acquisition occurs, the inventor or owner loses this managerial control, as the company brings in its own staff to facilitate the adoption of the new product into their business (Wodlinger, 2018). Most importantly, there is no guarantee that an idea or product will be acquired. Therefore, an owner must be sure of their position in the market and the potential of the idea for interest by a company, before the time and resources are spent.

3.2.3 Independent Start-Up

Beginning a start-up company to manufacture, advertise, and sell an idea or product is a commercialization method that provides the greatest freedom for an inventor or development team. According to medical technology device consultants, Class I and II devices are best to use

for creating a start-up, as Class III devices are typically too difficult to fund with this model. Class III devices require far more capital than could be withstood by an independent start-up, especially as the FDA regulatory process can be lengthy. Inventors need to surround themselves with experts in each part of a business, from legal and medical device sales, to manufacturing personnel and accountants. Complete control and long-term wealth accompany start-ups, as well as a high level of risk (Wodlinger, 2018).

Start-ups offer the inventor the ability to keep control of their product and technology, the intellectual property, and the route of their business. Start-ups allow the inventor to maintain ownership, unlike acquisitions which transfer this ownership to the acquiring company. On the other hand, start-ups have many disadvantages. The most concerning aspect of the start-up commercialization path is the need for large amounts of capital and cash. During the first year, the start-up may require tens of thousands of dollars per month, but this can increase dramatically as the entity ages (Hirsch, 2013). Owners and developers must also be dedicated to the start-up for a long life cycle. Hirsch notes that medical device start-ups time-to-exit take, on average, nearly nine years and by then the company will have spent upwards of \$50 million (2013).

3.2.4 Scaling Matrix

The project team developed a weighted scaling matrix in order to compare the three medical technology business model options for commercialization. This scale was decided on based on consulting research as well as how applicable it was to the cardiac patch. Licensing scored a weighted total of 65, with 87% applicability to the project goal and commercialization needs. Building an acquisition company scored a weighted total of 41, with 55% applicability to the project goal and commercialization needs. Building an independent start-up company scored

a weighted total of 34, with 45% applicability to the project goal and commercialization needs. The full scaling matrix can be found below in Figure 4 and Appendix A.

Number Ranking Matrix to Determine Route to Commercialization								
Notable Aspects	Technology	Build Value to License		Build Value to Acquire		Build Value to be Independent		
			Rating		Rating		Rating	
	Technology	Strong patent	5	Strong patent	5	Strong patent	5	
		Field of license establishes allowed uses of product	5	Watching parent company manage product after acquisition	1	Retain control of your products and future	5	
		Desire to stay focused on R&D of a product	5	Desire to introduce a new technology and exit	1	Desire to introduce a technology and manage it throughout its life	2	
		Product is in high demand	3	Product's technology is disruptive	2	Product's technology has strong value proposition, but not seriously disruptive	1	
		Desire to create a technology platform to introduce to many markets	5	Desire to create a single product and introduce it to a specific market	1	Desire for line of products within a specific market	1	
		Small initial capital needed	5	Large initial capital needed	3	Large initial capital needed	1	
	Costs	Financial	Royalties to fund next projects	5	Venture capitalists to back product development	3	Alternative funding to support company - not supported by venture capitalists	2
			Large, virtually free, sales force	5	Organize sales force to acquire sales prior to acquisition	1	Organize own sales forces for company lifespan	1
			Profit margins vary	2	Opportunity to get rich fast	5	Long-term wealth creation	5
		Time	No absolute job security	2	Setbacks often fatal to venture capitalist support	1	Success rides on satisfaction of investors and sales generated	2
			Class I, II or III	5	Class I, II or III	5	Only Class I or II - Class III too difficult to finance	1
			Make money "while you sleep"	5	Start-up company	1	Start-up company	1
	Market	End-date or long term	5	End-date in mind	3	Long-term	3	
		Hot market with significant barriers to entry (time, patent development)	4	Hot market with high growth potential	5	Any market	5	
		Have a single product synergistic to company portfolio	4	Have a single product synergistic to company portfolio	4	Have a line of products to dominate single market	1	
		TOTALS	Build Value to License	65	Build Value to Acquire	41	Build Value to be Independent	34
				87%		55%		45%

Key	
No applicability	1
	2
Neutral applicability	3
	4
Complete applicability Dr. Pins commercialization desires	5

Figure 4: Number Ranking Matrix to Determine Route to Commercialization

For a better representation of this matrix, the team changed the numbers into a color scale, with green being “complete applicability to Dr. Pins’ commercialization” and red being “no applicability.” This matrix can be seen below in Figure 5, as well as Appendix B.

Color Ranking Matrix to Determine Route to Commercialization								
Notable Aspects	Technology	Build Value to License		Build Value to Acquire		Build Value to be Independent		
			Technology	Strong patent	5	Strong patent	5	Strong patent
Field of license establishes allowed uses of product	5			Watching parent company manage product after acquisition	1	Retain control of your products and future	5	
Desire to stay focused on R&D of a product	5			Desire to introduce a new technology and exit	1	Desire to introduce a technology and manage it throughout its life	2	
Product is in high demand	3			Product's technology is disruptive	2	Product's technology has strong value proposition, but not seriously disruptive	1	
Desire to create a technology platform to introduce to many markets	5			Desire to create a single product and introduce it to a specific market	1	Desire for line of products within a specific market	1	
Small initial capital needed	5			Large initial capital needed	3	Large initial capital needed	1	
Costs	Financial		Royalties to fund next projects	5	Venture capitalists to back product development	3	Alternative funding to support company - not supported by venture capitalists	2
			Large, virtually free, sales force	5	Organize sales force to acquire sales prior to acquisition	1	Organize own sales forces for company lifespan	1
			Profit margins vary	2	Opportunity to get rich fast	5	Long-term wealth creation	5
	Time		No absolute job security	2	Setbacks often fatal to venture capitalist support	1	Success rides on satisfaction of investors and sales generated	2
			Class I, II or III	5	Class I, II or III	5	Only Class I or II - Class III too difficult to finance	1
			Make money "while you sleep"	5	Start-up company	1	Start-up company	1
Market	End-date or long term		5	End-date in mind	3	Long-term	3	
	Hot market with significant barriers to entry (time, patent development)		4	Hot market with high growth potential	5	Any market	5	
	Have a single product synergistic to company portfolio		4	Have a single product synergistic to company portfolio	4	Have a line of products to dominate single market	1	
	TOTALS		Build Value to License	65	Build Value to Acquire	41	Build Value to be Independent	34
				87%		55%		45%

Key	
No applicability	1
Neutral applicability	2
Complete applicability Dr. Pins commercialization	3

Figure 5: Color Ranking Matrix to Determine Route to Commercialization

Through the use of the scaling matrix and scoring system, the team found that the best go-to-market strategy for the cardiac patch was licensing with the highest score of the three options. The components of each type of company that were developed as a combination of insight from Medical Device Consultant Dr. Harold Wodlinger and additional components, the

team found through a combination of independent research and Professor Pins' desires for the future of this product. Specifically, the team referred to Dr. Wodlinger's lecture at Sunnybrook Hospital titled "Business Models Fundamentals in Medtech" to gain insight from an industry expert on the considerations taken when choosing the best path to commercialize a medical device.

After the components had been created, the team decided that the best way to conclude the recommendation for the best path of commercialization for Professor Pins' cardiac patch would be to add a number ranking system to the matrix in order to learn just how well each business model matched the desires of Professor Pins as well as the current development stage of the cardiac patch. When considering the ranking system, the team immediately ruled out a one through two or one through three systems as many of the components were not "yes" "no" or "maybe" questions. The team chose the numbers one through five because it allowed for extreme, neutral and partial matches to all be addressed making it easy to follow and also allowed for the numbers to be easily changed as development of the cardiac patch continues.

3.3 Cost-Benefit Analysis

3.3.1 Costs

Cardiac Patch Material Costs

The main ingredients for the cardiac patch included fibrinogen, thrombin, and vellum paper. A patch can have any number of threads incorporated into it, depending upon what size is desired. For the purpose of the MQP, the project team analyzed costs based on one cardiac patch consisting of a single frame made up of twenty threads. Thrombin is purchased from Sigma, Fibrinogen is purchased from MP Biomedical, and the vellum paper can be found at any local

consumer goods company. Individual thread formation and organization in the frame takes about two hours of work, excluding the time required for threads to dry overnight.

Currently, the development team produces patches on an individual basis. Taking the route of beginning a start-up or setting a goal of being acquired for commercialization purposes would cause a significant increase in costs to manufacture. According to McKinsey & Company, a consulting firm serving the medical device and pharmaceutical industries, the medical device industry spends, on average, about 76% of revenues on operations and manufacturing costs (Fuhr, 2013). These costs include cost of goods sold (41%), raw materials (17%), selling, general, and administration expenses (28%) and others (Fuhr, 2013). Additional manufacturing costs would also include a larger plant facility, proper sanitation supplies, adequate storage spaces, and quality processes. Cost savings could be met by buying patch materials in bulk through WPI's lab research suppliers. Otherwise, manufacturing the cardiac patch introduces a heavy cost burden for the development team.

Cardiac Patch Indirect Costs

Indirect costs for the development and commercialization of the cardiac patch and associated technology included FDA clinical approval, as well as the cost of securing intellectual property rights and patents.

For a Class III medical device, as classified by the FDA, a total estimated time of six to twelve years is estimated to complete clinical FDA approval. The total timeline can be divided up into five development stages including concept, technology, prototype, pre-clinical, and clinical development. Each development stage requires a different level of funding, starting with government grants from sources such as the National Institutes of Health (NIH), to late-stage angel investing. A total of between \$7 and \$10.5 million is required for the complete process of

running clinicals and gaining FDA approval. At the end of this process, the medical technology can be ready to be licensed out, acquired by a larger company, or developed enough to start an independent venture. This entire process is outlined in Figure 6 (Stathopoulos, 2013).

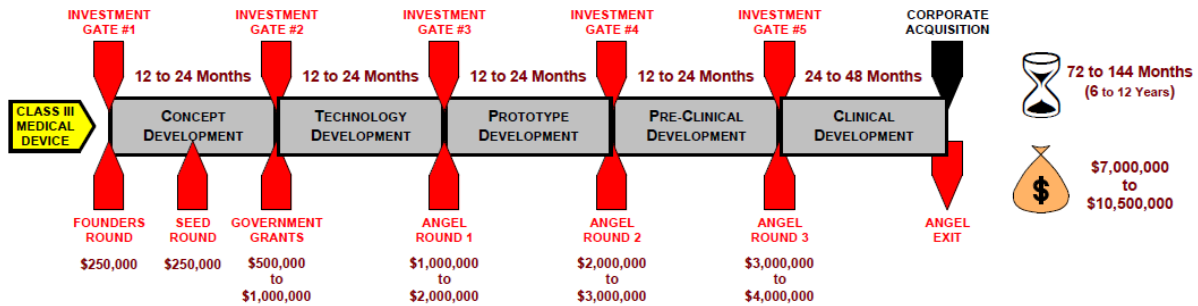


Figure 6: Timeline and Budget for FDA Approval of a Class III Medical Device, Stathopoulos, 2013

In order to successfully commercialize the cardiac patch, the associated technology must be secured by strong intellectual property. Patents for medical technology, including filing and administrative fees, typically cost between \$10,000 and \$35,000 (Davidov, 2013). Inventors from universities disclose their idea to the Office of Technology Transfer or Management on-campus. Licensing officers and intellectual property lawyers then evaluate the idea to ensure that the invention is novel, non-obvious, and can benefit society in some way. If the invention meets these criteria, the inventors and officers often file for a patent. As of 2016, universities reported an increase of 8.7% of invention disclosures and, similarly, patent applications filed were also up 5% (Hawkins, 2016).

Combining the cost of FDA approval and securing intellectual property for the cardiac patch results in a total estimated indirect cost of between \$7.01 and \$10.54 million, based on the assumption that both processes take a combined six to twelve years for completion. Table 2 shows three scenarios for determining the total indirect cost of commercializing the cardiac patch

technology, based on time for FDA approval and securing intellectual property, as well as below average, average, and above average cases for the costs of each. The ranges provided above for time and costs were used as the below and above average figures, while the average column was calculated by averaging the ends of the ranges for each of the criteria.

	<i>Below Average</i>	<i>Average</i>	<i>Above Average</i>
<i>Time (years)</i>	6	9	12
<i>Indirect Cost per Patch</i>			
<i>FDA Regulatory Process</i>	\$7.0 M	\$8.8 M	\$10.5 M
<i>IP Protection</i>	\$10,000	\$22,500	\$35,000
<i>Total Indirect Cost</i>	\$7.01 M	\$8.82 M	\$10.54 M

Table 2: Cases for Determining Total Indirect Cost of Commercializing a Cardiac Patch

Additionally, the project team calculated the indirect costs of commercialization on a per patch basis. The team estimated that with a below average case, the cardiac patch would reach 10% of the potential 688,000 patients who survive following a heart attack and now seek medical treatment (86% of those who survive the nearly 800,000 heart attacks annually). This resulted in the below average demand number of patches per year, rounded up, to be 70,000. The same calculations were performed for an average case of meeting 20% of potential patients, or 140,000 patches per year, as well as for an above average case of meeting 30% of potential patients, or 210,000 patches per year. These per year demands were then multiplied by the respective time frames to estimate a total production of patches over six, nine, and twelve years. Finally, the project team divided the total indirect cost for each time period (Table 2) by the total production of patches to estimate the indirect cost per patch. These calculations are summarized in Table 3.

<i>Time Period (years)</i>	6	9	12
<i>% of Patients</i>	10%	20%	30%
<i>Demand # of Patches (per year)</i>	70,000	140,000	210,000
<i>Total Patches Over Time Period</i>	420,000	1,260,000	2,520,000
<i>Total Costs, IP and FDA Approval</i>	\$7.01 million	\$8.82 million	\$10.54 million
<i>Indirect Cost per Patch</i>	\$16.70	\$7.00	\$4.20

Table 3: Cases for Determining Indirect Cost per Patch

The project team estimated the indirect cost per patch, including costs for intellectual property and FDA approval, to be \$16.70 after six years, \$7.00 after nine years, and \$4.20 after twelve years. Figure 7 shows the indirect cost per patch decreasing over time.

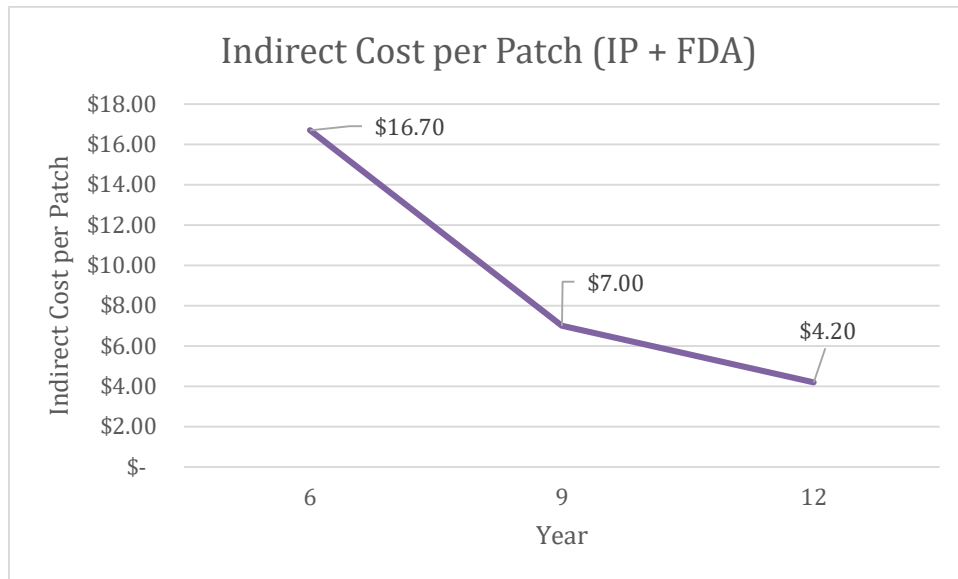


Figure 7: Indirect Cost per Patch Over Time

These calculations were based on several assumptions. The first assumption was that the developers would meet the potential patient population of 10%, 20% and 30%. Depending upon market conditions and acceptance of the cardiac patch technology, these percentages could be higher or lower. The second assumption was that production per year would be met, as well as stay consistent, throughout the estimated time period. Production numbers could realistically be altered due to increased competition too. It is also possible that if FDA approval and securing intellectual property rights takes longer than expected, costs per patch could increase from a

delay with initiating production. All in all, the project team was confident that production of the cardiac patch would increase over time to meet a higher demand, therefore spreading out the total indirect costs over a longer time period and reducing indirect costs per patch.

3.3.2 Benefits

Measuring the Value of a Cardiac Patch

The project team found, through the use of several Harvard Business School cases, including, “Tengion: Bringing Regenerative Medicine to Life,” (Ofek, 2014), that there were two best practices for calculating the value of emerging medical technology, including:

1. Savings from reduced future complications
2. Increase in patients' quality of life

In the case of the cardiac patch, these calculations would analyze the savings from reduced complications following a heart attack and the potential increase in quality of life following the implantation of a patch into a heart attack victim.

First, the project team acknowledged the potential savings that a cardiac patch might bring patients, by reducing the chance of many common post-heart attack complications. Many of the complications following a heart attack still negatively impact the heart and its daily functioning. Some of these complications, treatments, and average costs can be found in Table 4.

Complication	Treatment	Avg. Cost, U.S.
Arrhythmia	Implantable Cardioverter Defibrillator (ICD)	\$40,000
Heart Valve Disease	Valve Replacement Surgery	\$40,000
Coronary Artery Disease and Heart Failure	Angioplasty	\$25,000
	Coronary Artery Bypass Surgery	\$75,000
	Heart Transplant Surgery	\$500,000

Table 4: Common Complications Following a Heart Attack

Following a heart attack, those afflicted can experience an irregular heartbeat, or arrhythmia, as a result of the attack. An arrhythmia occurs when the heart's natural pacemaker is out of rhythm, the heart's conduction pathway is interrupted, in this situation by a heart attack, or the pacemaker is overcome by another part of the heart. The irregular beat can often be repaired by a temporary pacemaker or an implantable cardioverter defibrillator (ICD), which costs an average of \$40,000 (Esposito, 2014). Heart valve disease presents another common complication for those experiencing a heart attack, which requires heart valves to be repaired or replaced if severely damaged. A heart valve replacement surgery can cost about \$40,000 on average in the U.S. (Robinson, 2011). Most commonly, those who suffer through a heart attack and are left with damaged heart tissue face heart failure and coronary artery disease. Treatments range from angioplasty, inserting stents to open blocked arteries and vessels, to invasive coronary artery bypass surgery, each costing an average of \$25,000 and \$75,000 respectively (DeLong, 2017). If heart failure persists, many patients will need a heart transplant surgery which costs upwards of \$500,000 (Cox, 2017). Chronic conditions following a heart attack can include high blood pressure, high cholesterol, diabetes, depression, and others.

In order to calculate total savings, the following equation should be calculated for each complication:

$$\textit{Incidence} \times \textit{Avg. cost per incident}$$

If complications rise on an annual basis, the equation would be altered to include frequency per year and life expectancy, as follows:

$$\textit{Incidence} \times \textit{Frequency} \times \textit{Avg. cost} \times \textit{Years until avg. maximum life expectancy}$$

Once these calculations have been made for each complication, a sum is taken to show the total potential cost savings. This indicates the potential savings from reducing post-heart attack

complications and associated costs, that can result from the successful implementation of a cardiac patch.

Second, the project team measured the value of the cardiac patch through its potential increase in quality of life for patients. The quality of life measurement takes the value of a healthy year of human life and multiplies this by the percentage improvement that a cardiac patch can provide patients. The result provides an estimate of the increase in quality of life to patients who receive a cardiac patch. However, two important limitations were noted by the project team. First, further development is required before a percentage improvement can be calculated for the cardiac patch. Second, the value of a healthy year of human life can be debated when performing these types of calculations. As a result, the quality of life increase value of the cardiac patch may differ throughout development and should be used only as an estimated range of increase in value to patients.

Therefore, the cardiac patch development team should use both the reduced post-heart attack complication savings and increase in quality of life calculations in order to further show the value of the cardiac patch throughout the commercialization process.

Potential Income Stream from Licensing

Licensing offers a unique method of generating income from the intellectual property of medical device technology. Upfront license fees for the medical device industry range from between \$25,000 and \$50,000, depending upon the technology and market conditions. These upfront fees are collected at the beginning of the contract, after negotiations between licensees and licensors have been finalized. Royalties for the medical device industry are typically in the range of 0.5% to 7% (Shimasaki, 2009). A summary of these projected royalties can be seen in Table 5.

The following table lists general ranges for some financial terms that may be found in a licensing agreement. Note that the trend in most biotechnology licenses is a small up-front fee, high milestone payments, and mid-high royalties.

	Therapeutic/Biologic	Diagnostic/Medical Device
Typical up front license fee	\$25,000 – \$1,000,000	\$25,000 – \$50,000
Potential milestone payments	Varies from \$25,000 to multiple millions based upon the stages and technology	Varies from none to millions depending upon the technology
Estimated royalties	5% – 12%	0.5% – 7%
Estimated minimum annual royalties	\$50,000 – \$1,000,000 or more depending upon the technology	\$20,000 – \$100,000 or more depending upon the technology

Source: Shimasaki, C.D. (2009). *The business of bioscience: What goes into making a biotechnology product*. New York: Springer Science + Business Media.

Table 5: Comparison of Licensing Fees and Royalties

Payments are set out in a predetermined schedule during negotiations. Royalties can be set on a per product basis as it is sold, or calculated by the percent increase in operating margin that a licensee experiences due to the licensed intellectual property. Well established companies who act as licensees may be more willing to make cash royalties to licensors, since they have the necessary capital. On the other hand, smaller start-ups may offer licensors stock in the company, since cash flow is so restricted in this entity (Dr. Rawat, Personal Communication, January 30, 2018). Therefore, licensing provides an easy method for an inventor to make money from their intellectual property, without many of the risks associated with commercialization.

Chapter 4: Recommendations

The project team recommends that the best commercial pathway for the emerging cardiac patch technology is licensing. The team recommends that the WPI cardiac patch development team pursue a licensing agreement that, specifically:

1. Targets medical device companies, with or without an established cardiac patch division, as the licensee(s)
2. Has non-exclusive terms
3. Licenses the cardiac patch technology globally
4. Is industry-specific
5. Fits the technology into existing medical codes for insurance purposes

While the project team found that licensing will provide for the best commercialization strategy at the current stage of development, it is also important to note that this recommendation may change as the cardiac patch development process continues over time. This report analyzed two additional medical technology go-to-market strategies for use by the development team, if the commercialization process were to take a different route in the future.

4.1 Targets Medical Device Companies as Licensees

The project team recommends that Professor Pins and the development team seek licensing agreements with medical device companies as the licensees. The medical device companies can be either,

1. Those with an established cardiac patch division, looking for new technology, or
2. Those without an established cardiac patch division, looking to break into this industry

Medical device companies with well-established cardiac divisions may be looking for new technology in order to further drive innovation. Depending upon company needs, they may feel that the cardiac patch technology could fit into a different level of innovation, as seen in Figure 8.

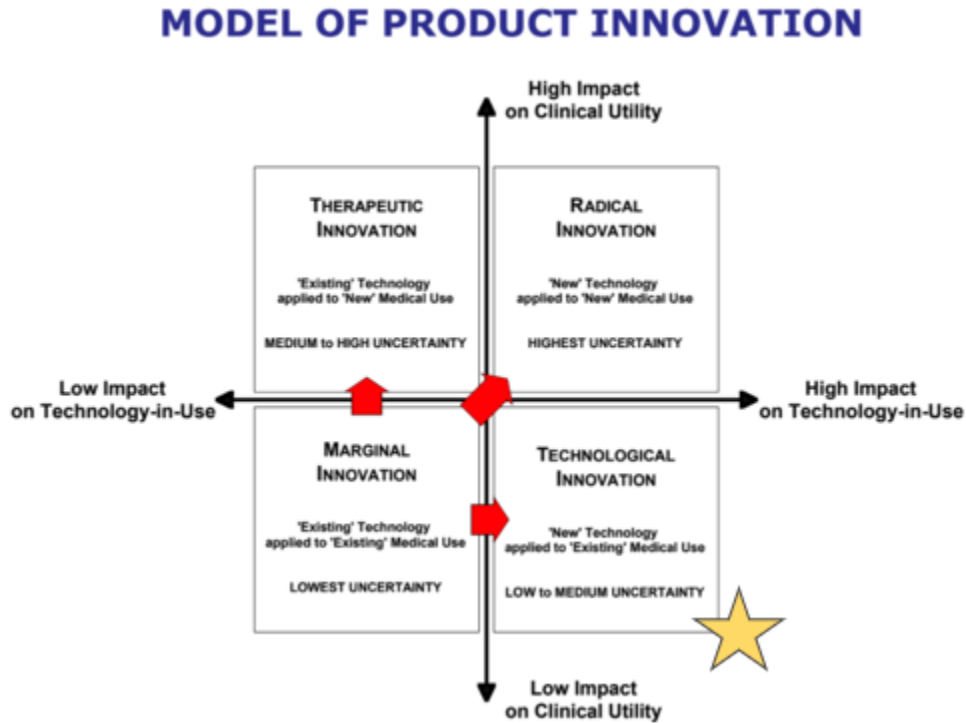


Figure 8: Model of Product Innovation for Medical Devices, Stathopoulos, 2013

The star here represents Professor Pins’ cardiac patch as a technological innovation: a new technology that can be applied to an existing medical use. Advantages of these companies being a licensee is that well-established capital budgets for cash royalty payments, as well as experience in the industry, so as to not misuse the technology. Medical device companies without an established cardiac division may be looking to expand into the industry, without the need for in-house research and development costs. However, these licensees may misuse the technology or misunderstand the market without experience in the industry. Both options allow for royalty payments and a way to get the cardiac patch technology to the market quickly, which is why the project team recommends them as the best licensee options.

A third option for a licensee is that of medical device start-ups, looking to break into a new and unexplored market. The advantage of this licensee over the others is that of attractive options for Professor Pins to stay more involved with the technology, marketing, and manufacturing efforts. However, due to restricted cash flow, start-ups are more likely to offer equity within the company over cash royalty payments, which is why these licensees would be the least recommended by the project team.

Because a licensing deal relies solely on the other companies' interest in the use of the inventor's technology, it is vital to establish potential customers early in product development. This leads the team to the next vital aspect of managing a licensing deal: being flexible. The owner of the intellectual property, thus likely the inventor of a product, is going to be extremely passionate about their product and the course that they think it should take. A licensing agreement or "field of license" allows those parameters to be identified early on in the agreement.

4.2 Has Non-Exclusive Terms

The project team recommends that the licensing deal have non-exclusive terms. Exclusivity refers to who is allowed to use the intellectual property rights, in terms of a licensing agreement (Shkopiak, 2018). Exclusivity gives all the rights to a single licensee, or in this case, a single medical device company. Non-exclusive rights allow the licensor to license the intellectual property to more than one single licensee, or multiple companies, start-ups, or other licensees. During negotiations, companies may offer higher royalties for exclusivity to their company for rights, so that competitors are not able to license the same intellectual property to compete. Licensors seek non-exclusivity, so that multiple licensees may exploit the intellectual property. The project team found that non-exclusivity was ideal for the licensing agreement because it is riskier for a licensor to have an exclusive deal. The licensee has the ability to shelf

the technology or drop out of the agreement, potentially leaving the licensor with nothing. However, non-exclusive deals are much less likely to be negotiated.

4.3 Licenses the Cardiac Patch Technology Globally

Licensing is one way to penetrate a foreign market, especially if that market is already closed off to imports. However, before a product is to enter a foreign market with a licensing agreement, it is crucial that exclusive property rights are obtained through a patent, copyright, or trademark (Gardner, 2013). Once those are obtained, there are six key components and provisions to be included in a foreign licensing agreement:

1. Foreign approval of licensed goods
2. Payment plans, currency conversion, as well as international tariff determination
3. Consent to jurisdiction
4. Choice of law
5. Dealing with conflicts through arbitration
6. Foreign patent

The project team recommends that the licensing agreement enters markets internationally, including within the United States, Europe, Japan, and China, based on their technology platforms and status in the medical device field. These nations all have strong medical device markets which means competition is high as there are products with patents already secured.

Asia Pacific dominated the overall market in terms of revenue share as they take up about 59% of the total revenue in the cardiovascular and soft tissue repair patch market (Grandview Research, 2016). This is due the large population base of this region, as well as their susceptibility to cardiovascular diseases that typically require surgery. Also, due to the constantly

improving healthcare structure, this region has a higher penetration of cardiac patches which can boost market growth. This region includes China, Japan, and Australia as main competitors in the cardiovascular and soft tissue repair market.

Cardiovascular disease is one of the leading causes of death in Asia and 57% of 16.5 million people who die from this disease annually are from Asia. This number is destined to continually increase as residents of Asia have changed their lifestyle, and are eating Western fast food, they are smoking more, and exercising less. Because of this, there is more of a focus on the diagnosis, treatment, and prevention of cardiovascular diseases, and a rising demand for medical devices in Asia. The current market in Asia is worth 11.5 billion USD with a 11% annual growth. In 2017, Asia took up 29% of the market, which is expected to grow to 38% in 9 years (MassDevice, 2012).

China's market for coronary artery disease patients is 19.8 million out of the total population of 1.38 billion people. With China's rapidly aging population, there is a greater need for medical devices to aid in the solution to the problem of coronary artery disease. Although a major portion of the medical device companies in China are foreign firms from the United States or Europe, local Chinese companies such as Lepu and MicroPort manufacture Class III Medical Devices (MassDevice, 2012).

Japan's market consists of a rapidly aging population with a rising number of people with diabetes as well as young smokers. This has greatly increased the number of people who suffer from cardiovascular disease in Japan, allowing for a growth in the cardiovascular device market. Japan has high government healthcare standards, which opens up the market for new interventional healthcare solutions.

Europe and the United States share the majority of the cardiac patch market. International companies tend to have their firms located in Europe because of their understanding of the market and the need for new approaches to medicine.

4.4 Is Industry-Specific

The project team recommends that the licensing agreement for commercialization of the cardiac patch technology be industry-specific. This would allow the development team to utilize the technology as a platform, for future applications. A licensing agreement for the cardiac patch technology, with non-exclusive and global terms, allows the patch to get to the market faster, in order to treat patients suffering from myocardial infarctions as soon as possible. However, due diligence with securing strong intellectual property rights will allow Professor Pins and the development team to continue researching to determine if the technology can be applied to other parts of the body, and, therefore, other industries, as well. This sets up the possibility for additional licensing agreements in the future, outside of the cardiac industry.

The team also strongly recommends that the development team use a Freedom to Operate opinion before filing for the patent. Before pursuing commercialization, it is crucial that *prior art*, or any evidence that one's device or invention is already known, is overcome in order to introduce a product.

4.5 Fits the Technology into Existing Medical Codes

Medical device coding is any extremely complex process vital to the success of any medical device. The project team recommends that the cardiac patch technology fits into existing medical code(s), as this will greatly speed up the process of FDA approval and insurance coverage for patients.

According to the Atticus Group, a business development firm for medical devices, coding acts as “the language of insurers” (The Atticus Group, 2017). Every aspect of a medical device, from the supplies all the way to the implantation procedures, is broken down in the seemingly foreign language of medical device codes. These codes are listed on insurance claims prepared by hospitals and doctors to ensure the proper payment by insurance companies for the service and use of the medical device. Proper coding for a medical device is vital to a streamlined and organized payment process.

The first step in establishing a coding sequence for any medical device is to apply to the American Medical Association (AMA) for Current Procedural Terminology (CPT) codes. CPT codes classify medical, surgical and diagnostic procedures into a simplified number system simplifying the vast number of procedures used in today’s healthcare system (Rouse, 2015). There are three categories in CPT codes broken down to numbers one through three, with more detail on each provided in Chapter 5.

4.6 Recommended Next Steps

Based on the team's recommendations, the next steps in order to evaluate the commercial pathway of the emerging cardiac patch technology should be to:

1. Secure intellectual property and patent position
2. Gain FDA (or equivalent) approval
3. Measure cardiologist/cardiac surgeon interest in the cardiac patch
4. Determine the medical code that best fits the properties of the patch, for easier adoption of the product by insurance companies
5. Explore additional niche markets with the technology platform

Additionally, the project team recommends that the cardiac patch development team take advantage of their close relationship with a university Technology Transfer Office. These offices at WPI and UMASS Medical are able to provide support to the development team throughout the product's clinical trials, FDA approval, and licensing royalty negotiations. The project team also recommends collaborating with a medical device consultant in order to gain access to seemingly confidential industry information.

Chapter 5: Discussion

5.1 Myocardial Infarction Causes

Most heart attacks occur after a blood clot forms and, with plaque build-up over time, blocks blood flow to and from the coronary artery (“Understanding Heart Attack,” 2017). These blockages are most commonly the result of coronary artery disease, or “atherosclerosis.”

Coronary artery disease is triggered by high cholesterol, high blood pressure, obesity, stress, and smoking (“Understanding Heart Attack,” 2017). Diabetes and heart disease can also increase an individual’s chances of suffering from a heart attack.

5.2 Other Current Medical Treatments and Solutions

Other medical treatments and solutions for myocardial infarctions include:

5.2.1 Balloon Stents

The insertion of a balloon stent has been a commonplace solution around the world to treat the effects of and prevent myocardial infarctions for over ten years with over two million people each year opting for this type of treatment (Medtronic, 2017). The procedure, called an angioplasty, is minimally invasive and extremely effective.

An initial angioplasty determines the exact location of any and all blockages in the coronary artery system that need to receive treatment. A catheter is inserted into the arterial system via a small insertion in either the leg or arm to the location(s) of the blockages using x-ray guidance (Medtronic, 2017). Once the wire is in place, a balloon is delivered to the blockage. The balloon is inflated and deflated multiple times to clear the site of plaque build up to allow blood flow to restore. Once complete, an additional balloon is sent via the catheter to the blockage site, but this time mounted with a stent. As the second balloon is inflated, the stent is

forced open and locked into place to hold the artery open as a permanent solution to keep the blockage site clear. This procedure instantly relieves clogged arteries proving extremely effective to treat current and potential issues of arterial plaque buildup that could in turn lead to a myocardial infarction (American Heart Association, 2015).

Advancements on this technology front have arisen from companies incorporating medication and drug delivery into this treatment. The introduction of drug delivering stents has come to market as well as the method of not using a stent at all and just using a drug-delivering balloon. Instead of attaching a stent to keep the artery open, Medtronic has begun coating the second balloon in the operation with an anti-proliferative medication. This has become another popular use of the balloon technology posing possibly more effective results than a traditional balloon-stent procedure.

The use of balloon stents and additional procedures is commonplace amongst hospitals across the world. A minimally invasive procedure that can virtually stop a heart attack, the benefits of this procedure are great for an emergency procedure.

Balloon stents have proven to be quite a short-term solution with restenosis rates being recorded between 3% to 20% within six months though some studies have found rates as high as 40% (Osterweil, 2017). Additionally, balloon stent procedures do not treat any issue that may have been damaged due to the previously blocked artery. Any damage that may have been done to the tissue of the myocardium is not addressed using this procedure. Ranging at costs of \$15,000 to \$50,000 as just a base cost, a balloon stent procedure is a high cost for a seemingly temporary solution (Medigo, 2018).

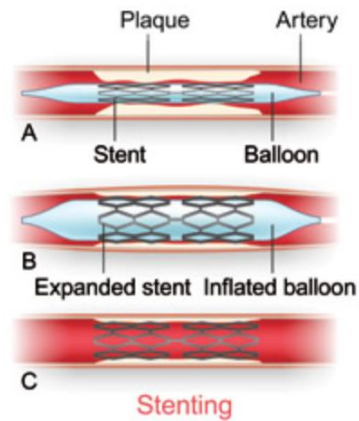


Figure 9: Balloon Stent Procedure, Livingston, 2015

5.2.2 Medication

Medications are commonplace in hospitals in order to provide physical relief to patients as well as reduce the effects associated with a patient who has suffered a myocardial infarction. According to the American Heart Association, there are eleven types of drugs used to treat the effects of a myocardial infarction. All of these drugs are aimed to solve varying issues that are the result of the occurrence of an infarct and have varying degrees of success (American Heart Association, 2017).

- Angiotensin-Converting-Enzyme (ACE) Inhibitor
 - Stops the production of the enzyme that produced angiotensin II which works to constrain blood vessels and raise blood pressure (Mayo Clinic Staff, 2016)
- Angiotensin II Receptor Blockers (or Inhibitors)
 - Prevents angiotensin II from performing its function of constricting blood vessels and raising blood pressure (Mayo Clinic Staff, 2016)
- Angiotensin-Receptor Neprilysin Inhibitors (ARNIs)
 - Neprilysin inhibitor and benefits of ARB drugs (American Heart Association, 2017)

- If Channel Blocker (or Inhibitor)
 - Slows heart rate (American Heart Association, 2017)
- Beta Blockers
 - Slows heart rate (American Heart Association, 2017)
- Aldosterone Antagonists
 - Blood thinner (American Heart Association, 2017)
- Hydralazine and isosorbide dinitrate
 - Recommended for African American patients as a solution to reducing hypertension (Taylor, 2004)
- Diuretics
 - Rid the body of excess fluids and sodium that can cause unnecessary strain on the heart to process (American Heart Association, 2017)
- Anticoagulants
 - Blood thinner
- Statins
 - Prevent the production of hydroxy-methylglutaryl-coenzyme A reductase, a cholesterol producing enzyme (Ogbu, 2018)
- Digoxin
 - Controls rhythm of heart beat through increasing production of ATPase, an enzyme that promotes contractile movements within the heart (Ogbu, 2018)

Though unique combinations of these individual drugs are often used to treat each patient, it is clear that there is not one definitive drug solution that can be taken in the long run.

5.2.3 Direct injection

Direct injection is another solution to the problem of myocardial infarctions. Direct injection can be done numerous ways: intracardiac injection, surgical injection, as well as robotic injection.

Intracardiac injection can be done directly through the skin in order to provide therapeutic cells to the heart. This is done by directly inserting a needle into the myocardium of the heart chamber. This form of injection method is minimally invasive as well as inexpensive as it uses common procedures and syringes. There can be a few drawbacks with this method as there can be risks to the patient that is receiving this injection. Lacerations of the myocardium as well as a collapsed lung can occur if the procedure is not done properly. The stomach wall may also be punctured. Although this procedure is minimally invasive, the insertion of this needle can be quite painful for the patient (Lamberg, 2013).

The next type of injection occurs during heart surgery. It is an additional procedure that can be done to improve heart function after surgery. Although this surgery provides direct contact with the heart as the surgeon has access to it, it is much more invasive. A syringe is used to directly inject the autologous cells into the heart. This method is not fully supported by surgeons as it is in addition to open surgery, and because it does not have a high success rate (approximately 11%), surgeons are not as willing to perform it (US National Library of Medicine, 2012).

Finally, there is new technology out there in order to perform a robotic injection paired with a hydrogel injection. The HeartLander, a crawling robot used for this injection, is minimally invasive and has the ability to perform these injections accurately. Through the control of a surgeon, this robot can enter the chest through an incision within the sternum, adhere to the heart, travel to the correct location of the infarct, and administer cell therapy. Although this

testing has only been done on pig hearts, it has seen success. This robot can move to any location on the pericardial surface after a 10 mm incision has been made. This robot can reach the target location of the treatment through sensor data that determines where the infarct is, as the surgeon is the one who guides it remotely. Once the robot reaches the desired location, it is in a stable state in order to provide the therapeutic treatment with a needle. For myocardial infarctions, a dye is injected into the site from outside of the animal, and then cells can be delivered to the correct depth of the myocardium. The benefits of this method include its stability, localized sensing, no potential for lung deflation, as well as access to the heart. However, this method seems as if it will be an expensive one as sensors are required as well as the purchase of the robot itself for each procedure. The other procedures are done using medical tools that are already on hand, making this the more expensive choice (Robotics Institute, n.d.).

5.2.4 IV Drip

The next type of injection is done intravenously through an IV drip directly into the radial vein. When focusing on the heart, there is a high concentration of cells that are being delivered to the body through this drip and travel directly to the affected area of the heart. As this is the most minimally invasive of its competition, there can be complications due to the path of delivery. As these cells are delivered directly into the bloodstream, they can pass through other organs of the body such as the lungs and can form clumps of cells within the body. Doctors who inject these cells have no way to control where these cells attach in the body, giving it a very small chance that these cells attach to the heart wall rather than other organs (Martins de Oliveira, n.d.).

5.2.5 Cardiac Patches

The function of a cardiac patch is to replace the dead or damaged tissue that develops as a result of a myocardial infarction. Most commonly used in the operating room today are

synthetic, a-cellular patches. Traditionally, patches are constructed of either polyethylene terephthalate (PET) or (expanded polytetrafluoroethylene) ePTFE.

The thermoplastic polymer PET is best recognized by the brand name Dacron. Dacron is a highly favored biomaterial to use as the scaffolding material of a cardiac patch due to its promotion of endothelialization while maintaining virtually no calcification or tissue overgrowth in the process (An Introduction to PET, n.d.). In comparison to PET grafts, ePTFE grafts are used much less, but are the basis to a wide number of grafts created by one of the top material science companies in the world, Gore. ePTFE poses the benefit of lower thrombogenicity, or the tendency of a material that comes in contact with blood to cause a clot, as well as not being physiologically harmful to the site in which it is placed. However, it can be mechanically weak, which is a disadvantage when it comes to heart function when trying to imitate the mechanical and electrical properties of the heart (The Properties and Advantages of ePTFE, 2016).

5.3 Stakeholders

5.3.1 Biomedical Engineer

Biomedical engineers are important stakeholders in the cardiac patch industry as they are the ones who will continue to build the technology. They constantly invent and discover new solutions to problems within the healthcare field, such as the creation of the cardiac patch to solve the prevalent cardiac disease issue that is plaguing the world. Biomedical engineers have an important role in development, as the patch has the potential to be used for more than just cardiac infarcts. Within the cardiac patch market there is a high growth potential, which is beneficial to biomedical engineers as they will constantly have a need for their new and innovative research.

5.3.2 Medical Device Companies

Medical device companies are important stakeholders in the cardiac patch industry as they are the ones who sell the products that the biomedical engineers invent and create. With a strong patent and the approval of this cardiac patch, these companies would be able to add this cardiac patch to their repertoire through a licensing arrangement, giving them an advantage in the market that they are constantly trying to be the main competitor in. These companies play an important role as they would be responsible for manufacturing the patch as well as getting it to the market. With that, this patch would be able to generate revenue for the medical device companies as well as strengthen their brand.

5.3.3 Hospitals

Since cardiac diseases are the leading cause of death, hospitals are increasingly looking for improved technology in order to better treat those suffering from myocardial infarctions. Often times, when a patient suffers a heart attack, they are admitted to the coronary care unit, or CCU. There they are monitored closely by a cardiac care team. Hospitals and staff will share in the responsibility for risk related to the cardiac patch technology. It is up to the hospital to ensure safety and efficacy of the patch, as well as to determine which patients would be best suited for implantation. The hospital is also responsible for employing cardiologists who implant the cardiac patch and monitor the patient over time, as well as training the staff on the proper use of the new technology. While the cardiac patch may provide benefits to the hospital with decreased rate of mortality from heart attacks, the hospital would also be responsible for taking on the risks and complications of bridging the gap between the technology manufacturers and patients.

5.3.4 Cardiac Surgeons

Cardiac surgeons would be taking on extremely high risk when adopting this new technology into their practice. At stake is the lives of their patients, their career and reputation in the medical field. The surgeons are responsible for not only the successful implantation of the cardiac patch but ensuring the long-term success of the device for the patient.

5.3.5 Patients

The patient who receives a cardiac patch is the stakeholder that would be most affected by the commercialization of this new technology. Ensuring that the cardiac patch delivers on the functions it promises to deliver is vital to patients.

It is imperative to the success of this cardiac patch that the consumer has a clear understanding of the benefit this product poses to them over the competition. This includes the technology benefits of the device over the competition, recovery process and long-term behavior of the device. It is the team's opinion that Dr. Pins should market this device as having the advantage of having tunable mechanical and biologic functions. Dr. Pins has identified a significant gap in the market for a device that also integrates with the tissue restoring mechanical functions and contractility. While the cardiac patches on the market today provide structural support for the heart after the removal of damaged myocardial tissue, Pins' patch does this as well as incorporate tunable functions.

5.4 Risk Assessment

When commercializing medical device technology, there are various levels of development risk depending upon if the technology is "new" or "existing," as well if the clinical use of the technology is "new" or "existing." The uncertainty of risk increases as both the technology and clinical use are newer to the market (Stathopoulos, 2013). Likewise, low

uncertainty matches a technology already in the market with an existing medical use. The project team found that the emerging cardiac patch technology from Professor Pins and the development team at WPI fits into a “new” medical technology category, with an “existing” clinical use. The technology specific to this patch is new and improved, while the clinical use is existing, since cardiac patches in general already exist. Figure 10 shows the level of development risk scale, as well as where the cardiac patch fits indicated by the star.

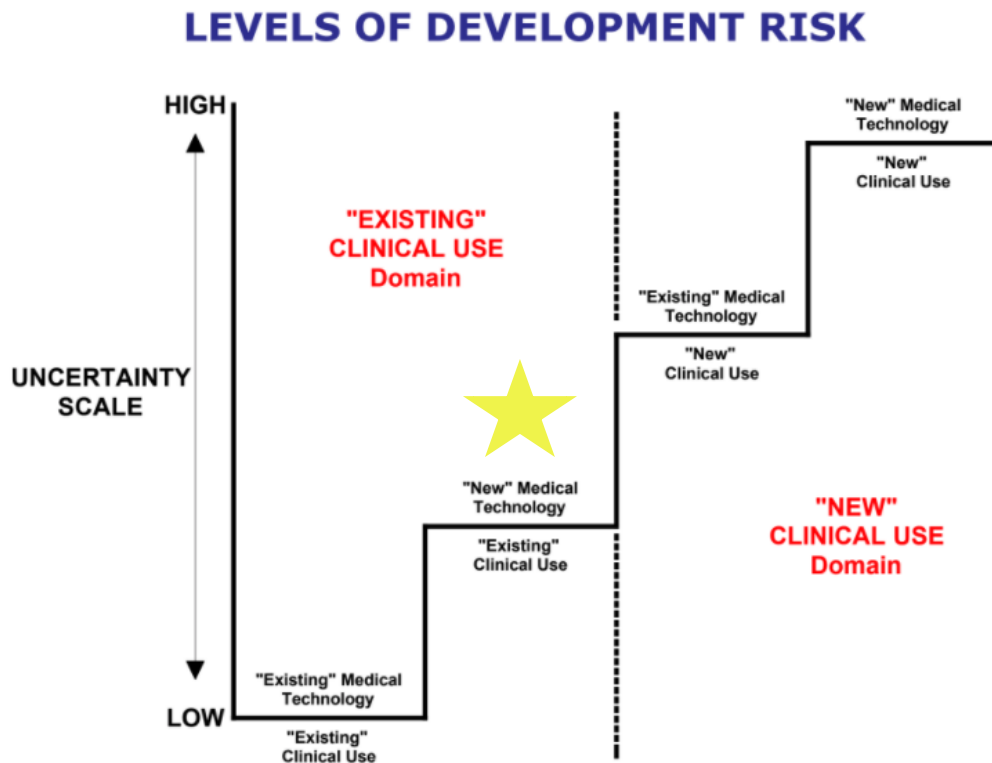


Figure 10: Levels of Development Risk, Stathopoulos, 2013

In addition to development risk levels, there are also a number of legal, financial, and regulatory risks associated with commercializing the cardiac patch technology. Legal risks include gaining proper patents for the technology to protect against infringement, as well as adhering to contracts with any partners involved in the process. Financial risks include restricted cash flow, and the reliance on capital raised from investors and venture capitalists. Regulatory

risks refer to the timeline for FDA approval, since a Class III medical device requires extensive clinical studies, extending the time needed for the total approval process. Changes in compliance laws throughout different regions may also add regulatory risk, as the changes would need to be tracked when licensing globally.

5.5 Intellectual Property

5.5.1 United States of America

In the United States of America, the rights to intellectual property are permitted in the form of a patent. The United States Patent and Trademark Office (USPTO) is the government organization responsible for reviewing the grants and applications submitted by prospective inventors and the distribution of the patents (USPTO, 2015).

Securing a patent for an invention is a common procedure for anyone looking to capitalize on their invention. Securing a patent for a technology builds a large amount value for the owner by developing intangible assets, developing legitimacy in the industry, total control of the technology (Thayer, 2013).

There are three types of patents distributed by the USPTO. The names and definitions given by the USPO are as follows:

“Utility patents may be granted to anyone who invents or discovers any new and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof. Design patents may be granted to anyone who invents a new, original, and ornamental design for an article of manufacture. Plant patents may be granted to anyone who invents or discovers and asexually reproduces any distinct and new variety of plant” (USPTO, 2015).

After the patent is distributed, it is the responsibility of the patent owner to protect their property from others using it, not the USPTO. A common fallacy is that a patent grants the

owner the right to make, use and sell the invention in the United States. On the contrary, a patent gives the inventor of the product the rights to seek legal action toward anyone infringing on one's patent (USPTO, 2015) (Frisina, 2015). A patented process or technology can contain other processes or technologies that are protected by another party preventing the free use of one's invention. For examples, a patent for invention "C" could use an implantation process protected by patent "A" as a core component of the production of the product. Without a legal license to use patent "A", patent "C" cannot be created, used or sold without infringing upon patent "A".

In 2016 alone, there were a total of 4,520 patent infringement cases in the United States of America; all which came with a high price tag attached to each (Brachmann, 2017). According to the 2017 Report of the Economic Survey published by the American Intellectual Property Association, the average legal bill for any party involved in a case, where less than \$1 million is at risk, is \$800,000 (Nayak, 2017). Where the stakes are higher with \$1 to \$10 million dollars at risk, the infringement case costs, on average, \$1.7 million dollars (Nayak, 2017).

In order to avoid situations like this, early investigation in the form of a Freedom to Operate Opinion has become highly favored by industry experts, even going as far as to be seen just as important as having a patent.

5.5.2 Freedom to Operate Opinion

A Freedom to Operate Opinion (FTO) is a service that aims to avoid patent infringement lawsuits or the standstill of a patent. This is accomplished with an FTO by investigating outstanding or pending patents that may affect one's ability to use the filing patent. The sole purpose of an FTO is to ensure that one is able to freely practice the protected technology in the industry, which is one of the most vital components for commercializing any product.

A FTO gives a potential investor, partner and of course the inventor a professional document that can ensure to a certain degree, the allowance of the use of the patent in the industry. From the inventor's point of view, the attractiveness of an FTO is that, if filed early enough, it offers the filer the ability to alter their product or service before filing as to ensure the allowance to use after they have been granted the patent.

In the medical device industry specifically, an FTO is an extremely attractive investment to make considering the amount of time and money that goes into the development of a medical device. An FTO is best to be conducted as soon as possible in the development of a medical device so as to ensure that all aspects of the device are allowed to be freely exercised down to the way the device may be implanted. Seeking out an FTO as soon as possible will allow for efficiency and time for the proper adjustments to be made to any patents the exercising of the use of the device may be currently infringing upon. However, in an industry such as cardiac medical devices where the market is growing, getting a proper FTO is extremely difficult.

5.5.3 International

A U.S. patent protects this intellectual property of an invention only within the United States of America and its territories. Patent laws differ from country to country and must be individually investigated and filed in order to obtain intellectual property protection outside of the United States (USPTO, 2009).

5.6 Medical Device Coding and Insurance

When a medical device is ready for distribution, after receiving clearance from the FDA, a plan for reimbursement must be well established in order to simplify the exchange of the product for capital. Though hospitals and doctors are the entities that use medical devices, more often than not, they do not directly pay for them. Instead, insurance companies are usually

responsible to cover their customers' expenses. Insurance agencies can be simply divided into two primary categories of private entities (Blue Cross Blue Shield, Harvard Pilgrim, etc.) or government entities (Medicare, Medicaid, etc.). No matter the third party though, any third party requires baseline components within the three categories of coverage, coding and payment (Mensch, 2006).

Category 1 codes contain the latest and greatest in medical device procedures (Rouse, 2015). These procedures are FDA approved and seen as commonplace in hospitals and doctors' offices worldwide (Rouse, 2015). Furthermore, CPT codes are divided into six primary categories labeled evaluation and management, pathology and laboratory anesthesiology, radiology, surgery and medicine.

Category 2 codes are used in conjunction with Category 1 codes to further define the characteristics of the procedure performed. This set of codes is not mandatory but is only used when Category 1 codes are present on the insurance claim. Category 3 CPT codes are temporary codes appointed to breakthrough and upcoming medical technologies that may just be breaking into industry. Procedures that hold Category 3 codes may not have FDA approval or even any clinical results but are a part of ongoing human studies (Rouse, 2015). CPT codes are used in conjunction with an additional set of codes called ICD-10 codes.

ICD-10 or International Classification of Disease, replaced the ICD-9 codes in 2015, ICD-10 was made mandatory for use of anyone covered by the Health Insurance Portability Accountability Act, including all hospitals, physicians and insurance companies (AthenaHealth, 2017). There are currently more than 68,000 codes in the ICD-10 alone showing the challenges presented in classifying a device. The ICD-10 codes are vital to the continuous improvement of

the healthcare system in their specificity of diseases that further allow the creation of data and patterns to be analyzed by industry experts about diseases.

The Healthcare Common Procedural Coding System II (HCPS II) is the third and final set of codes needed to be addressed in the commercialization of a medical device. The HCPSII system is defined by the Centers for Medicare and Medicaid Services (CMS) as CMS, “a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT code set jurisdiction, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office.” (Centers for Medicare and Medicaid Services, 2015).

5.7 Regulatory Standards

Regulatory standards vary from country to country, as this next section addresses the regulatory process for the United States, Japan, China, and countries within Europe.

5.7.1 United States

Within the United States, in order for a medical device to be able to be put onto the market, it must pass the Food and Drug Association (FDA) regulatory process. The general FDA process can be seen below in Figure 11.

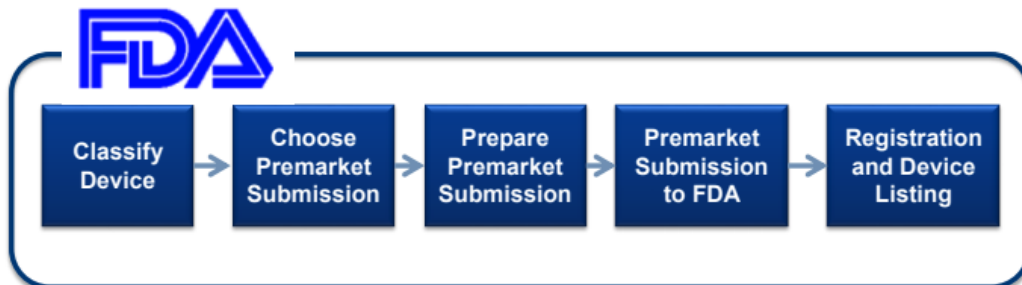


Figure 11: Food and Drug Association Pathway

The FDA requires that clinical trials done in the United States, with five hundred to one thousand patients in order for it to pass through and onto the market. Medical devices in the United States require Pre-Market Approval (PMA), or the scientific and regulatory process of the FDA that a Class III medical device needs to be reviewed for to evaluate the safety as well as usability of said device. A PMA in order to be passed by the FDA requires sufficient data and evidence that the medical device in question is safe and efficient for its intended use, which can be through the clinical trials mentioned above (Center for Devices and Radiological Health, n.d.). The entirety of this process can cost between \$5 and \$10 million, spanning over a period of five to ten years. The regulatory process in the United States, in detail, can be seen in Figure 12.

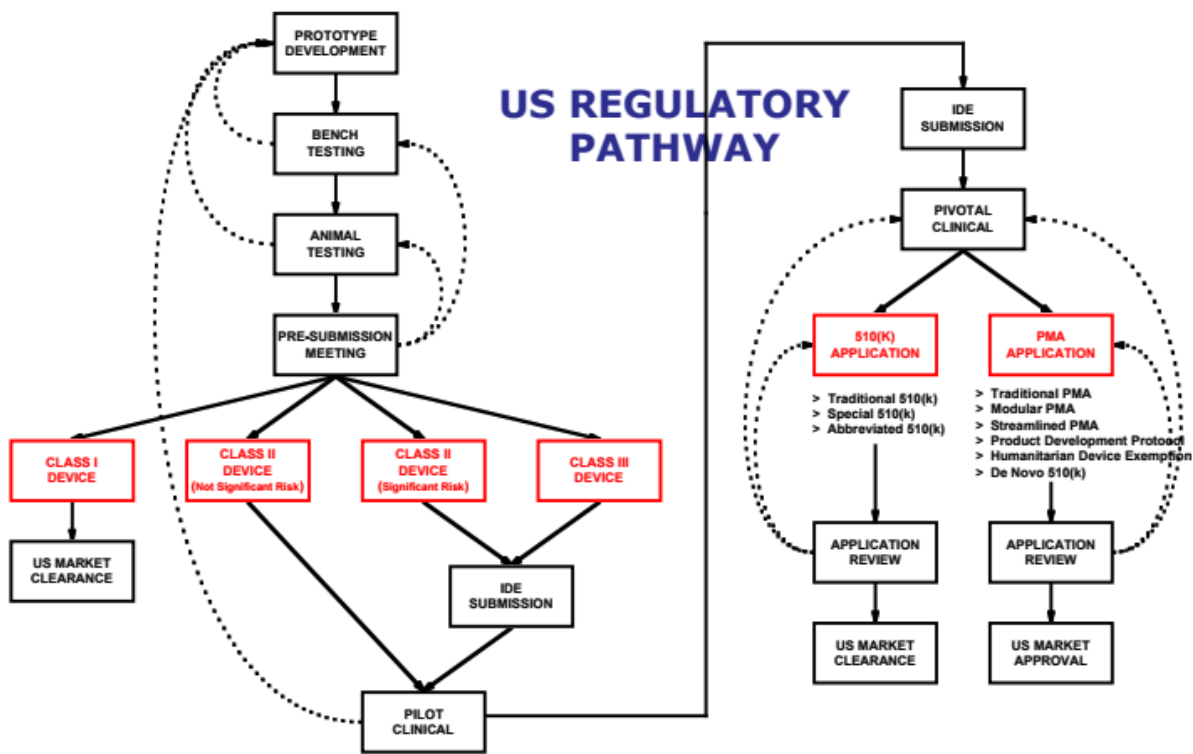


Figure 12: United States Regulatory Pathway, Stathopoulos, 2013

5.7.2 Japan

In Japan, as within the United States, a Class III medical device has to go through an agency for approval prior to entering the market. Medical devices in Japan need approval from the Pharmaceuticals and Medical Devices Agency (PMDA), which is a Japanese governmental organization that functions similarly to that of the FDA as it is in compliance with ISO 13485, which is the agreed upon international standard and requirements for quality as well as for the regulatory processes of medical devices (ISO-Medical Devices, 2018). However, the process for each device that goes through the PMDA varies based on the risk associated with the device, rather than based on the type of device. In regards to local clinical trials, the number of patients for each trial is based on the risk associated with the device as well. For a high risk device such as a cardiac patch, there are from four hundred to six hundred patients required. The costs for completing these clinical trials are high and can be lengthy in order to gain the certificate of approval. However, once approval is gained for that device, the certificate never expires, unlike in other nations.

5.7.3 China

The process for getting approval in China has similarities and differences to that of other nations. The device must go through the Chinese Food and Drug Association (CFDA). However, when bringing a device that is created in an outside nation from China, there must be approval from the home country of said device through a certificate of free sale as well as a certificate to the foreign government. This can lengthen the process as it really is two separate approval processes. Once the device is approved in its home nation and has retained an ISO 13485 certificate, there must be an agent located in China that will coordinate the CFDA device

registration. With a Class III device, there must be local clinical testing done in China as well as a product comparison to one of equivalence that already exists in China. The number of patients for clinical trials can vary as well as fees, but the time frame for approval can be the longest as there is authorization required from home nations and all documentation of the results and evaluations must be in the simplest form of Chinese before they can be submitted to the CFDA for approval. Once approved, the certificate does not expire for five years (Chinese Food and Drug Association, 2013).

5.7.4 Europe

In certain nations of Europe, the equivalent of the FDA process within the United States is a process through the European Medicines Agency (EMA). However, with medical devices, they must receive a CE mark, or a mark that indicates a product conforms to health, safety, and environmental standards of a nation within Europe, before it can be distributed to other nations within the European Union. In order to meet CE guidelines, clinical trials must be completed locally within Europe with patient numbers that are equivalent to those of similar products that have already been approved. Once a CE certificate gets received, the firm can then register the device to be distributed within certain countries. This certificate is valid for up to a year and is up for auditing in all years after. The process of receiving a CE mark can cost from two to three million dollars.

5.8 Team Growth and Examination

Since all students in the team majored in Management Engineering with a concentration in Biomedical Engineering, each has received an education in both the business and biomedical engineering spectrums at WPI. Finding this balance, in addition to a diverse advisory team

background, the team had to ensure that the material they chose to highlight in team presentations as to satisfy not only themselves, but the professors on the project with a wide variety of professional backgrounds. Throughout the first seven weeks, the team had to overcome the challenge of developing a language and style of presentation that could hold the attention and understanding of both a businessman and biomedical engineer. Originally, the project team faced this challenge through week seven. Next, the respective functional requirements were to be established. Perfecting these processes took the rest of the term and was done in conjunction with exploring more about the technology which began in week six.

By spending a lengthy amount of time focusing on the decomposition, the team learned the importance of having proper resources and not trying to “reinvent the wheel”. Maintaining confidence in presentations and having proper factual support was something that the project team learned was vital for acting as consultants to Professor Pins on the project. This allowed the project team to support their stance knowing that they put the work in to eliminate other options and determine that the decision was factually supported. Before taking action, it was important to evaluate and plan the work ahead, so the use of axiomatic design was key in creating a fully utilized and organized roadmap for future weeks.

Additionally, the team discovered the importance of only choosing one specific, and narrow, problem to tackle. In the beginning of the project, the team was enthusiastic about developing an entire business plan and value proposition for Professor Pins’ cardiac patch. The team's research and writing included analyzing patents and intellectual property on the device, evaluating a number of different possible business routes, and analyzing competition and need for the product in the marketplace. After a few meetings with the project team's advisors, Mr. Joe Vignaly, and Dr. Yael Schwartz, the team quickly realized that trying to achieve all of these

different pieces would be an impossible task. The project team soon came to the conclusion that, despite each of these being an important problem in themselves, they could only focus in one of these areas for the project. This realization provided the project team with improved focus on what the MQP actually was, and how they were able to produce a valuable and useful project in the end.

Finally, the team learned the importance of collaborating with industry experts who have the experience to catalyze their thinking process and understanding of the problem at hand. Going into this project, the team expected to tackle this issue amongst only themselves and project advisors. The primary takeaway from the first seven weeks of the project was that, although group discussion and brainstorming are important, ultimate success relies on insight from industry experts who have experience completing such projects. Speaking with those such as Joe Vignaly and Yael Schwartz helped the project team pick up common themes among commercialization, which gave the project team a true starting point for the project.

While the project team was confident in the final go-to-market commercialization strategy recommended to the cardiac patch development team at the conclusion of the project, it should be noted that since the cardiac patch technology is still emerging, commercialization strategies and considerations could change with changes to the product, regulatory process, team functioning, and other outside factors impacting commercialization in the near future. All in all, the project team was able to provide next steps for the cardiac patch development team in order to have the highest probability of success at commercializing the cardiac patch.

Chapter 6: Conclusion

The project team worked with professors from both the Foisie Business School and Biomedical Engineering Department at WPI to address the problem of evaluating the commercial pathway of emerging cardiac patch technology developed on-campus. The team felt that this goal was achieved through the final recommendations provided to the cardiac patch development team, with a plan for successful commercialization.

The project team first had to decompose the problem at hand. Through the use of axiomatic design, the project team was able to divide the problem up into three main objectives which would lead to commercial success. The team analyzed the target market population, as well as projected market growth, to establish the unmet need and healthy competition necessary for a proper value proposition to initiate the commercialization process.

The team then evaluated how to generate income from commercialization. Through contact with medical device industry consultants, three go-to-market strategies were options for commercializing the cardiac patch, including licensing, acquisition, and start-ups. The project team developed a scaling matrix in order to compare and contrast the applicability of the cardiac patch technology with each strategy. Based on the project team's analysis, licensing was rated the highest and deemed to be the best option for commercialization at this stage of development.

In addition, the project team analyzed costs and benefits of commercializing the cardiac patch technology. Patch materials and costs were summarized following contact with the development team's biomedical PhD students. Indirect costs were estimated based on ranges for the cost of FDA approval and securing intellectual property rights, as well as demand projections for serving the target population of those seeking treatment following a heart attack. The project team also established metrics for measuring benefits of the cardiac patch, using various Harvard

Business School cases. These metrics included the decrease in cost from reduced post-heart attack complications and increase in patient quality of life from the cardiac patch.

With these results, the project team had to recommend the best route of commercialization to Professor Pins and the cardiac patch development team. In order to do so, the team further analyzed the regulatory and intellectual property requirement for commercializing a Class III medical device. The team felt strongly that research and results led to a licensing agreement being the best go-to-market option for commercialization at the time.

Therefore, the team recommended that a licensing deal for the cardiac patch technology should look for medical device companies with or without established cardiac divisions to be licensees, have non-exclusive terms, license the technology globally, be industry-specific, and utilize existing medical codes for insurance purposes. The project team felt that these considerations would provide for the largest potential royalty earnings, fastest route to helping the most amount of patients, and pave the way for future commercialization options with intellectual property set for a platform technology.

Based on the results and recommendations, the project team recommended next steps to the development team for the successful commercialization of the emerging cardiac patch technology. In order to increase the likelihood of success, the development team must secure strong intellectual property and gain FDA approval for the technology. The cardiac patch technology should then be introduced to cardiologists and cardiac surgeons to gauge interest in the technology and make appropriate changes during clinical development. Finally, the development team must determine the medical device code for insurance coverage and can then explore additional niche markets that benefit from the same technology platform.

As a result of the completion of the project goal, the project team felt that a framework was established for the cardiac patch development team to use throughout the commercialization process. By examining the target population, market growth, potential income generated, costs and benefits, and various intellectual property and regulatory considerations, Professor Pins and the cardiac patch development team will be able to effectively weigh the advantages and disadvantages of each of the commercialization pathway options. Through the use of a number of scientific considerations and business tools provided by this MQP, the cardiac patch technology will surely be commercialized successfully, for the benefit of an array of stakeholders involved in the process.

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Appendices

Appendix A: Number Ranking Matrix

Number Ranking Matrix to Determine Route to Commercialization						
	Build Value to License	Build Value to Acquire	Build Value to be Independent	Rating	Rating	Rating
Notable Aspects	Strong patent	Strong patent	Strong patent	5	5	5
	Field of license establishes allowed uses of product	Watching parent company manage product after acquisition	Retain control of your products and future	5	1	5
	Desire to stay focused on R&D of a product	Desire to introduce a new technology and exit	Desire to introduce a technology and manage it throughout its life	5	1	2
	Product is in high demand	Product's technology is disruptive	Product's technology has strong value proposition, but not seriously disrupt	3	2	1
	Desire to create a technology platform to introduce to many markets	Desire to create a single product and introduce it to a specific market	Desire for line of products within a specific market	5	1	1
	Small initial capital needed	Large initial capital needed	Large initial capital needed	5	3	1
	Royalties to fund next projects	Venture capitalists to back product development	Alternative funding to support company - not supported by venture capitalists	5	3	2
	Large, virtually free, sales force	Organize sales force to acquire sales prior to acquisition	Organize own sales forces for company lifespan	5	1	1
	Profit margins vary	Opportunity to get rich fast	Long-term wealth creation	2	5	3
	No absolute job security	Setbacks often fatal to venture capitalist support	Success rides on satisfaction of investors and sales generated	2	1	2
Class I, II or III	Class I, II or III	Only Class I or II - Class III too difficult to finance	5	5	1	
Make money "while you sleep"	Start-up company	Start-up company	5	1	1	
End-date or long term	End-date in mind	Long-term	5	3	3	
Hot market with significant barriers to entry (time, patent development)	Hot market with high growth potential	Any market	5	5	5	
Have a single product synergistic to company portfolio	Have a single product synergistic to company portfolio	Have a line of products to dominate single market	5	4	1	
TOTALS	Build Value to License 65 87%	Build Value to Acquire 41 55%	Build Value to be Independent 34 45%			
Key						
1 No applicability						
2 Neutral applicability						
3 Complete applicability Dr. Pius						
4 Commercialization desires						
5						

Appendix B: Color Ranking Matrix

Color Ranking Matrix to Determine Route to Commercialization				
Notable Aspects	Build Value to License			
	Technology	Financial	Time	Market
	Strong patent Field of license establishes allowed uses of product Desire to stay focused on R&D of a product Product is in high demand	Strong patent Watching parent company manage product after acquisition Desire to introduce a new technology and exit Product's technology is disruptive	Strong patent Desire to introduce a technology and manage it throughout its life Product's technology has strong value proposition, but not seriously disruptive Desire for line of products within a specific market Large initial capital needed	Strong patent Retain control of your products and future Desire to introduce a technology and manage it throughout its life Product's technology has strong value proposition, but not seriously disruptive Desire for line of products within a specific market Large initial capital needed
	Desire to create a technology platform to introduce to many markets Small initial capital needed Royalties to fund next projects Large, virtually free, sales force	Venture capitalists to back product development Organize sales force to acquire sales prior to acquisition	Desire to create a single product and introduce it to a specific market Large initial capital needed Venture capitalists to back product development Organize sales force to acquire sales prior to acquisition	Desire to create a single product and introduce it to a specific market Large initial capital needed Venture capitalists to support company - not supported by venture capitalists Alternative funding to support company lifespan Long-term wealth creation
	Profit margins vary No absolute job security Class I, II or III Make money "while you sleep" End-date or long term	Setbacks often fatal to venture capitalist support Class I, II or III Start-up company End-date in mind	Opportunity to get rich fast Setbacks often fatal to venture capitalist support Class I, II or III Start-up company End-date in mind	Success rides on satisfaction of investors and sales generated Only Class I or II - Class III too difficult to finance Start-up company Long-term
	Hot market with significant barriers to entry (time, patent development) Have a single product synergistic to company portfolio	Hot market with high growth potential Have a single product synergistic to company portfolio	Hot market with high growth potential Have a single product synergistic to company portfolio	Any market Have a line of products to dominate single market.
	67% 13% 7% 13% 0%	26% 7% 20% 7% 40%	20% 0% 13% 27% 40%	20% 20% 67%
	80% 13%	33% 47%	33% 47%	
	Build Value to License	Build Value to Acquire	Build Value to Acquire	Build Value to be Independent
	Key			
	No applicability			
	Neutral applicability			
	Complete applicability Dr. Pins commercialization			

Appendix C: 5 C's Analysis

5 C's Analysis				
Context	Company	Customers	Competition	Collaborators
PESTEL Analysis	Product Line 1. A-cellular patch 2. "living" patch 3. Application of technology elsewhere	Medical Device Companies 1. Looking for new patch technology 2. No patches - looking to bring one in	Balloon Stents	Product Development Prof. George Pins Prof. Glenn Gaudette Prof. Kristen Billar Kevin Corwell Marianne Kanelias Megan O'Brien Elizabeth English
	Technology Cardiac patch with fibrin thread scaffolding		Medication Intracardiac Injection	Regulatory Todd Keller Greenberg Traurig, LLP
	Reputation WPI VitaThreads Professor Pins' credentials		Intracardiac Injection Surgical Injection Robotic Injection	Suppliers Fibrinogen Supplier Thrombin Supplier Vellum Paper Supplier
	Culture R&D focused University environment		IV Injection	MP Biomedicals Sigma Aldrich Borden Riley Denril
	Company Goals "Fix people with heart attacks"		Polymer Fibrin	Manufacturers TBD
			Cardiac Patches	

<http://www.netmba.com/marketing/situation/>

Appendix D: Strengths, Weaknesses, Opportunities, Threats (SWOT)

SWOT Analysis	
Strengths	Weaknesses
NIH Grant backing the technology	Competitive market
WPI reputation	Much more additional research needed before interest
Accredited Engineers	Increasing popularity of preventative measures to heart health
Cost effective	No definitive timeline for development
Early development stages of product	Medical device sales tax
Innovative technology	U.S. regulatory processes
Geographic Location (Boston)	
Opportunities	Threats
Substantial predicted market growth	Growing competition in cardiac patches
Applicability of technology to other products	Cybersecurity
Increasing aging population (demographics)	Lack of future funding
Less stringent international business	"Product commoditization"
	Freedom to operate

Appendix E: Project Timeline & Gantt Chart

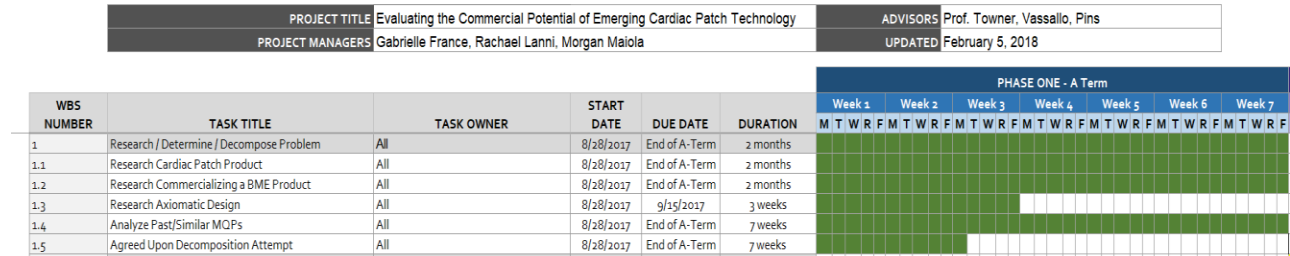


Figure 1: Project weeks 1-7

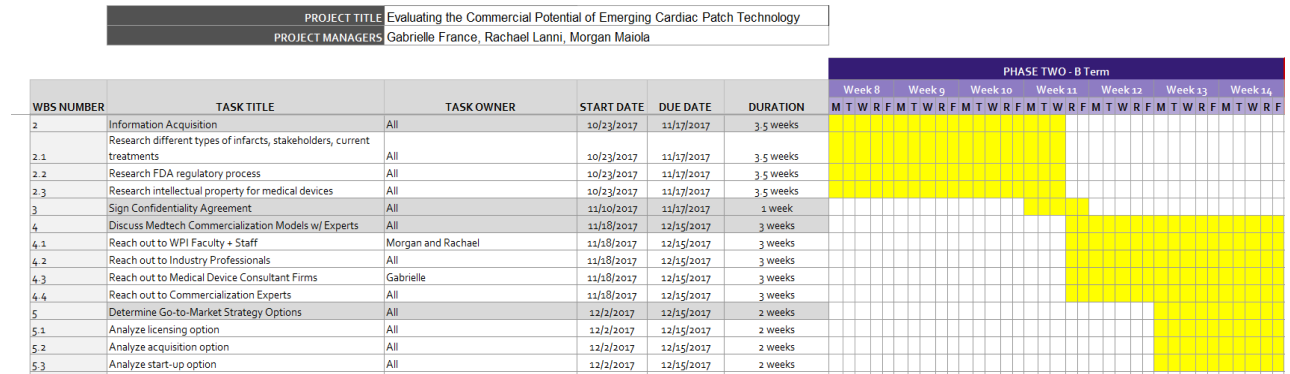


Figure 2: Project weeks 8-14

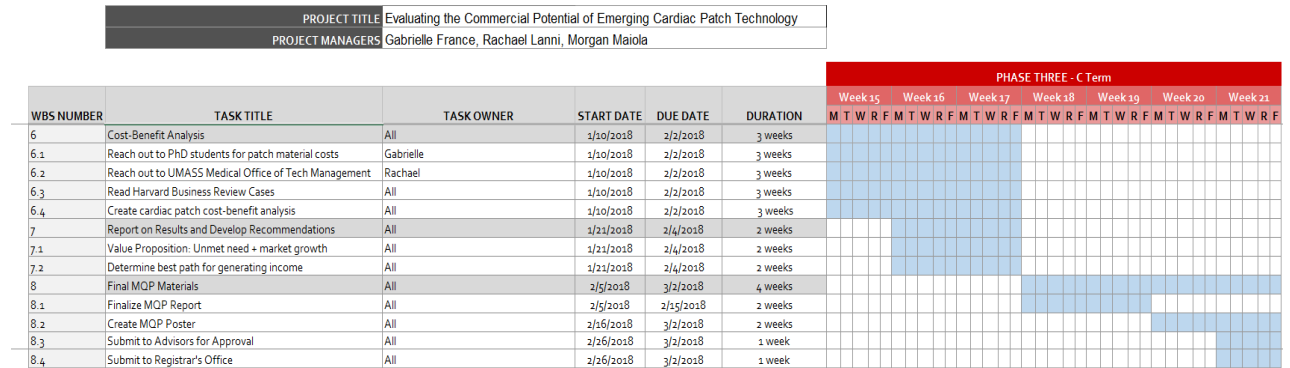


Figure 3: Project weeks 15-21