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What is Useful and Novel? The Collision between Intellectual Property Protection and Regulation Regarding Medical Devices

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**WHAT IS USEFUL AND NOVEL? THE COLLISION
BETWEEN INTELLECTUAL PROPERTY PROTECTION
AND REGULATION REGARDING MEDICAL DEVICES.**

BY JAMES SUTHERLAND

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I. Introduction

The United States Patent and Trademark Office (USPTO) issues patents as a means of protecting the intellectual property for the inventors of medical devices such as hip arthroplasty implants that fulfill the requirement of being both useful¹ and novel.² However, patents are issued for these devices prior to undergoing regulatory evaluation by the United States Food and Drug Administration (FDA) to establish their safety and their effectiveness. Furthermore, one of the main mechanisms the FDA has utilized for the evaluation of safety and effectiveness is the 510(k) process, which allows regulatory approval based on a device being “substantially equivalent” to a device that had previously been granted FDA approval.³ Consequently, the USPTO is providing patent protection for medical devices that have not had their utility established because their safety and clinical effectiveness have not been confirmed by the regulatory process, and their novelty is questionable because the regulatory approval relies upon a demonstration of “substantial equivalence”⁴ to a previously approved implantable device. The problem with the current timeline of the patent process and subsequent regulatory evaluation of medical devices has been demonstrated in recent years by the extensive litigation involving metal-on-metal total hip implants. The patenting and regulatory evaluation processes must be modified so that the utility and novelty of medical devices is established before such devices receive intellectual property protection by the patent process.

¹ 35 U. S. C. § 101 (2006).

² 35 U.S. C. § 102 (2011).

³ 21 USC 360c (2017), Notes of Decisions “Premarket approval.”

⁴ *Id.*

In order to realize the impact of this issue on society as a whole and on the medical device manufacturing industry in particular, one must understand the procedure of total hip replacement (THR)⁵ and its related technology. This will be reviewed first.

Armed with an understanding of the medical procedure and the associated medical devices that are implanted in patients during the process, the procedures for protecting the associated intellectual property of the devices will next be reviewed.

Following this the regulatory evaluation process of the FDA will be examined. Dissecting this process will demonstrate the dichotomy that currently exists between the protection of intellectual property afforded by the USPTO and the clinical evaluation mechanism of the FDA.

Next, the recent litigation involving metal-on-metal hip implants will be discussed with a particular emphasis on the associated costs and societal impacts. Part of this discourse will include a consideration of the policy arguments of the interplay between intellectual property protection and the regulation and evaluation of that property.

The discourse will conclude with consideration of the options by which the process may be overhauled and with specific recommendations on the best course of action.

⁵ This procedure, at times, will also be referred to as “total hip arthroplasty” or “THA.”

II. Total Hip Replacement Surgery History

The development of medical devices has had a dramatic socioeconomic impact on the health of citizens of the United States. The vast majority of these important discoveries have been developed within the last one hundred years. One of the most significant medical devices developed in the mid-twentieth century is the modern, low-friction total hip arthroplasty.⁶ It is one of the few medical devices that has resulted in both an improvement in the quality of life, due to decreased pain and increased activity for patients as well as decreased mortality of patients when compared to age matched controls of patients who have not undergone the operation.⁷ The evolution of this operation and the associated implantable medical devices has had a significant impact on the lives of millions of individuals in the United States and around the world.

⁶ See JOHN CHARNLEY, *LOW FRICTION ARTHROPLASTY OF THE HIP: THEORY AND PRACTICE* (Springer-Verlag 1979).

⁷ Jane Barrett et al, *Survival Following Total Hip Replacement*, 87(9), *J Bone Joint Surg Am*, September 2005 at 1965.

Modern hip arthroplasty is generally attributed to the efforts of the British surgeon Sir John Charnley in the early 1960's.⁸ Charnley's hip design involved a metallic head articulating on a plastic acetabular component.⁹ About the same time Charnley was developing a metal-on-plastic hip another designer, George McKee, began developing hip arthroplasty components that utilized a metal head articulating on a metal acetabular component.¹⁰ This device was patented in the United States in 1972.¹¹ The timing of these developments—especially the efforts of George McKee—are particularly important because they pre-date the advent of the Medical Devices Act of 1976. Over the ensuing sixty years, there has been an intensive debate about which of the types of components is the safest and most effective.

During the last decade, extensive and expensive product liability litigation of the metal-on-metal type of implant may have effectively resolved this debate.¹²

⁸ Stephen R. Knight, Randeep Aujla, and Satya Prasad Biswas, *Total Hip Arthroplasty – over 100 years of operative history*, *Orthop Rev.* v. 3(2), Sep. 6, 2011; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3257425/>.

⁹ JOHN CHARNLEY, *supra* note 12 at 41. Charnley's initial hip design actually used a Teflon acetabular component, but he subsequently abandoned this bearing surface when it did not perform as mechanically anticipated.

¹⁰ G. K. McKee, *Development of Total Prosthetic Replacement of the Hip*, 72, *Clin Orthop*, September-October 1970, at 85.

¹¹ U.S. Patent No. 3801989 A (filed Oct. 30, 1972).

¹² *See In Re: DePuy Orthopaedics, Inc., ASR Hip Implant Products Liability Litigation*, 753 F. Supp. 2d 1378 (MDL, 2010).

A. Technology

Hip arthroplasty surgery is performed through one of several surgical approaches in patients and takes about one and one-half hours to accomplish.¹³ During the process, the surgeon moves between or cuts through the muscles of the hip, opens the capsule of tissue around the hip, and dislocates or pops the ball of the upper femur (head) out of the socket of the pelvis (acetabulum). The femoral head is removed with a saw. The acetabulum is prepared with a series of spherical, cheese-grater like instruments progressively increasing in size. A type of roughened metal cup of slightly greater size and typically made of titanium is impacted into the acetabulum. The inner portion of the cup may then have a surface inserted into it that is comprised of either high density plastic, ceramic, or metallic cobalt-chrome alloy on which a new femoral head will articulate. The upper femur is then prepared with a series of instruments. A metallic stem most commonly made of titanium and of appropriate size is inserted into the upper femur. The stem typically has a bare neck on which is placed a head of one of varying sizes that is comprised of either ceramic or of a cobalt-chrome alloy.

¹³ For a complete discussion of the various surgical approaches to the hip, see Stanley Hoppenfield, Piet Deboer, *Surgical Exposures in Orthopaedics: The Anatomic Approach*, 302-357 J.B. Lippincott Company, 1984.

B. Current Technology

In 2016, the orthopaedic device industry generated revenue of \$48.1 billion, and a nearly \$7 billion was specifically related to implant hip arthroplasty components.¹⁴ Hip implant technology revenue therefore accounts for approximately fifteen percent of the total implant device market. Other sectors of the orthopedic device implant market would include prosthetic joint implants such as total knees, shoulders, and elbows; fracture fixation hardware such as various plates, screws, and rods; and spinal stabilization hardware such as pedicle screws, rods and fusion plate systems. There are several reasons hip implants comprise this percentage of the market and for similar reasons it is also expected that the hip implant market will continue to grow.

¹⁴ Carolyn LaWell, *Orthopaedic Industry Revenue Reaches \$48.1 Billion*, Orthoworld, Apr. 21, 2017, https://www.orthoworld.com/index.php/publications/orthoknow_content/orthopaedic-industry-revenue-reached-48-1-billion-worldwide-in-20.

First, it is estimated that the demand for total hip replacement will continue to grow as a result of the general aging of the population and the demand of the population to maintain an active lifestyle. Epidemiological data has been difficult to harvest regarding THR from a national perspective, since there is no mandatory total joint arthroplasty registry as currently exists in other countries like the United Kingdom. There is, however, an ongoing initiative for developing a national Joint Registry Program. At this time, it is currently voluntary. The program began in 2010 as a not-for-profit 501c(3) organization involving fifteen voluntarily participating hospitals.¹⁵ Only in 2016 was the registry recognized as such by the American Association of Hip and Knee Surgeons (AAHKS), and as of 2017 there were just over one million joint replacements being tracked in the registry.¹⁶ This presently accounts for one of seven million calculated total hip and knee components currently implanted in patients in the United States.¹⁷

Second, hip replacement surgery is increasingly being performed in younger individuals who wish to maintain an active and demanding lifestyle. When originally conceived and designed, THR was primarily to be an operation for older individuals. Currently, it is not uncommon for patients in their forties to undergo joint replacement surgery.

¹⁵ See AMERICAN JOINT REPLACEMENT REGISTRY, <http://www.ajrr.net/about-us/about-our-organization/about-history-milestones> (last visited on Apr. 19, 2018).

¹⁶ *Id.*

¹⁷ See Hilal Maradit Kremers et al, *Prevalence of Total Hip and Knee Replacement in the United States*, 97, J Bone Joint Surg, Sept. 2, 2015, at 1386.

Third, more complex revision hip surgery will be required because individuals who are having their hips replaced are living longer, and their lifespan is exceeding that of their replaced prosthetic joints. This necessitates even more complex and expensive revision or repeat joint replacement surgery. Again, the actual epidemiological data are difficult to estimate, but when considering the increases in primary (first) total hip replacements and revision (re-do) total hip replacements, there is an expected growth of 174 percent for primary total hip replacements and 137 percent for revision total hip replacements by the year 2030.¹⁸

Fourth, in an effort to subvert the inevitable mechanical wear properties of prosthetic hip components, the biomedical device industry is attempting to develop strategies to decrease the wear of implanted devices and to increase the lifespan of these same devices. This has resulted in implant manufacturers seeking new technologies to achieve this goal. These efforts have followed several pathways.

Manufacturers have sought to improve the manner in which these various devices are fixed to the bone, and two basic mechanisms exist to accomplish this. Either the components are “cemented” into place utilizing a biomedical polymer known as polymethylmethacrylate, or they are placed in “press-fit” fashion by machining the femur or the acetabulum (or both) to a size slightly smaller than the components that are implanted. The implanted components are then pounded into place and initially held by the mechanical interface between the bone and the metallic parts. When “press-fit” fixation is utilized, the components are designed in such a way that the bone will actually grow to the implanted devices over an approximately six-week period.

Device manufacturers have sought to preserve the native bone stock in patients by decreasing the size of implanted components. This has resulted in a decrease in the amount of bone removed at the index operation. The rationale is that by minimizing the initial removal of bone at the index operation, more bone will be preserved for future operations, should they become necessary.

¹⁸ A. Patel, G. Pavlou, R.E. Mujica-Mota, A.D. Toms, *The Epidemiology of Revision Total Knee and Hip Arthroplasty in England and Wales*, 97-B, Bone Joint J, July 29, 2015 at 1076.

Finally, and most importantly for this discussion, implant manufacturers have sought means by which to modify the bearing surfaces of the parts that articulate and rub against each other in the artificial hip joint. Bearing surfaces currently involve one of several permutations: (1) a metal ball that articulates on a plastic liner within the socket of the artificial hip joints; (2) a metal ball that articulates on a metal socket within the socket of the artificial hip joint; (3) a ceramic ball that articulates on a plastic bearing within the socket of the artificial hip joint; and (4), a ceramic ball that articulates on a ceramic bearing within the artificial hip joint. While some of these various combinations are “new,” the history of how arthroplasty developed is relevant to understanding the issue.

C. Economic Impact

It is anticipated that there will be a substantial increase in both primary and revision THR as projected from the year 2005 to the year 2030.¹⁹ As can be expected, this will result in a substantial economic burden on the United States health care system. Furthermore, from the current year to 2030, it is reasonable to anticipate that there will be technological advances necessitating intellectual property protection—most likely by way of the USPTO-- as well as medical device regulation and approval by the FDA.

¹⁹ S. Kurtz, K. Ong, E. Lau, F. Mowat, and M Halpern. *Projections of Primary and Revision Hip and Knee Arthroplasty in the United States from 2005 to 2030*, 89(4), J Bone Joint Surg Am, April 1, 2007 at 780. Primary THR is expected to increase by 174 percent; revision THR is expected to increase by 137 percent.

The cost for the surgical event alone of total hip arthroplasty is currently measured at approximately \$30,000. For revision hip arthroplasty it is \$38,000 per event.²⁰ “The enormous growth in hip arthroplasty may be justified by the fact that, despite its high cost, total hip replacement (THR) is an extremely cost-effective treatment intervention.²¹ As previously stated, THR is not simply a procedure performed on the elderly. “The demand for THA in patients younger than 65 years also is increasing, further increasing the disease burden of revision THA.”²² Even more concerning is that all projections are, at best, estimates, and are frequently underestimated in that the “actual number of revision THAs in 2006 exceeded the projected number of revision THA by >10,000 cases.”²³

These data all point to a significant growth in this area of the healthcare market. They also likely indicate an increase in the development of new technologies produced by manufacturers and inventors who will have a vested interest in protecting their intellectual property investments.

III. Utility and Novelty

A. History

In order to qualify for a patent, there has been a longstanding requirement that a patent applicant must demonstrate that an invention fulfills the requirements of novelty and utility.²⁴

²⁰ See R. Bitton, *The Economic Burden of Osteoarthritis*, 15(8) *Amer Journ Man Care*. 2009, at S233-235; see also J. N. Katz JN. *Total joint replacement in osteoarthritis* 20(1), *Best Pract Res Clin Rheumatol*, 2006 at 145.

²¹ *Id.*

²² Nho SJ et al, *The Burden of Hip Osteoarthritis in the United States: Epidemiologic and Economic Considerations*. 21(Suppl) *JAAOS*: 2013 at S1.

²³ See *id.*; see also S. Kurtz, *supra* note 19.

²⁴ *Supra* notes 1 and 2.

The consideration of both novelty and utility as patent requirements necessitates a historical review of these elements. As the development of American jurisprudence is founded in the traditions of English common law, so it is true that the authors of the Constitution framed the concept of early United States patent law on historical English precedents.²⁵ The earliest English concept of patents was based on ad hoc, discretionary royal grants. These grants from the Crown were initially focused on the development and the furtherance of new aspects and avenues of trade and economic growth. The protection of the rights of inventors was not considered when the Crown was granting patents.²⁶ Early patents were not seen as a “right” to intellectual property protection of an inventor. “Petitions contained recitals of utility[,]”²⁷ but it was not until the early seventeenth century that “the new common law thinking about monopolies began to stress novelty as an essential element of lawful patents”²⁸ As British colonies were established in North America, the patent system in the Colonies mirrored the system in England. However, there was no unified patent system spanning the early nation. Even after the Revolutionary War, the individual states retained the rights to protect and regulate intellectual property, as there were no provisions written into the Articles of Confederations. It was not until 1789 that the “U.S. Constitution changed this situation and laid the foundation for national patent and copyright regimes.”²⁹

²⁵ Oren Bracha, *Owning Ideas; The Intellectual Origins of American Intellectual Property, 1790-1909* at 12-19 (Cambridge University Press, 2016).

²⁶ *Id.*

²⁷ *Id.* at 17.

²⁸ *Id.* at 18.

²⁹ *Id.* at 47.

The authors of the Constitution specifically enshrined what was to become known as the “intellectual property clause”³⁰ in Article I, Section 8, clause 8 whereby it was established that “The Congress shall have Power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”³¹ Utilizing its newly granted authority, Congress passed the Patent Act of 1790.³² The Patent Act provided for patents of “any useful art, manufacture, engine, machine, or device, or any improvement therein not before known or used.”³³

The Patent Act of 1790 was later replaced by the 1836 Patent Act which again stressed the requirements of utility and novelty; furthermore, the 1836 Act established the “Patent Office [as] a distinct and separate bureau in the Department of State”³⁴ This and other types of intellectual property have been entrusted to the United States Patent Trademark Office (USPTO).³⁵ The regulation of these devices once invented, however, is currently under the auspices of the Food and Drug Administration.³⁶ There is, at present, a substantial disconnect between the legal framework under which these the intellectual property of medical devices is protected by patent law and subsequently approved for use in the public domain.

³⁰ *Id.*

³¹ U. S. Const. Art 1, § 8, cl. 8.

³² SHELDON W. HALPERN, KENNETH L. PORT, SEAN B. SEYMORE, FUNDAMENTALS OF UNITED STATES INTELLECTUAL PROPERTY LAW, at 155-158, (Wolters Kluwer 5 ed. 2015); *see also* Act of Apr. 10, 1790, ch. 7, I Stat. 100.

³³ *Id.*

³⁴ *Id.* at 157.

³⁵ 35 U.S.C. § 2 (2017).

³⁶ 21 U.S.C. § 301 (2017).

In order to protect the intellectual property aspects of the growing orthopaedic market, inventors have been relying on the patent process to protect their economic interests.³⁷ Countless patents have been issued for orthopaedic implant designs, surgical instruments used to insert the devices, and even for protective clothing used while performing the procedure.³⁸ Patents were sought by Charnley and by George McKee for their pioneering implants in the latter half of the twentieth century.³⁹ More recently, a Patent Number U.S. 5904720 A was issued to Johnson & Johnson Professional, Inc., the parent company of DePuy Orthopaedics, for a hip joint prosthesis with a metal-on-metal articulation between the prosthetic femoral head and the acetabular prosthetic component.⁴⁰ These are the types of components that were subsequently released after regulatory approval as substantial equivalents for implantation into patients worldwide.

Given recent events in the realm of medical devices, perhaps it is time to re-evaluate how the intellectual property of these devices is protected.

³⁷ *Supra* note 1.

³⁸ *Supra* note 6; U. S. Patent No. 3667456 A (filed Nov 19, 1970); U. S. Patent No. 3625206 A (filed Nov 3, 1969).

³⁹ *See* U. S. Patent No. 4327449 A (filed Jun 26, 1980); *see also* U. S. Patent No. 5904720 A (filed Aug 12, 1997).

⁴⁰ U. S. Patent No. U.S. 5904720 A (filed May 18, 1999).

B. Current Statutory Structure of Novelty and Utility

1. Novelty

The current statutory language governing patent law has most recently been updated in the Leahy-Smith America Invents Act of 2011.⁴¹ It requires that devices be, among other things, novel⁴² and useful.⁴³

Specifically, the requirement for novelty indicates that a patent may be granted to an individual unless the invention was previously patented or described in a printed publication or was available to the public commercially as set forth in the elements of 35 U.S.C § 102. The courts have upheld that “[d]esign patent infringement occurs only when the accused design is ‘substantially the same’ as the claimed design.”⁴⁴

⁴¹ P.L. 112-29, Sept 16, 2011, 125 STAT. 284.

⁴² 35 U.S. C. § 102 (2011).

⁴³ 35 U. S. C. § 101 (2006).

⁴⁴ Sun Hill Industries, Inc. v. Easter Unlimited, Inc 48F. 3d 1193, 1196 (U.S.C.A, Fed Cir, 1995).

When inventions are not new, they are said to be “anticipated by prior art.”⁴⁵ In order for prior art to defeat an alleged new invention’s claim of novelty, three conditions must be fulfilled: (1) the prior art’s invention date must pre-date the new invention development; (2) the prior art must be strictly identified; and (3) the prior art’s description must be “enabling”—that is, it must be sufficiently described such that a person having ordinary skill in the realm of the art described would be “enabled” to re-create the invention.⁴⁶ As will be discussed later, one of the critical aspects of the recent production and sale of hip arthroplasty implants has been a reliance on the FDA’s 510(k) process for approval. This process provides for the approval of implants that have been previously invented and are “substantially equivalent” to formerly approved medical devices.⁴⁷ If devices are determined to be “substantially equivalent,” it raises the issue of how such devices would fulfill the definition of novelty.

Novelty has been established from the earliest days of patent legislation vis a vis the Patent Act of 1790, as an essential requirement for an invention to receive a patent. Yet, the concept of substantial equivalence for FDA regulatory purposes would seem to contradict the element of novelty.

2. Utility

Analyzing the requirement for utility would appear to be intuitive. Implantable hip devices would be seen to be useful if they are capable of functioning as a prosthetic hip for an extended period of time.

⁴⁵ S. Halpern et al, *supra* 32 at 167.

⁴⁶ S. Halpern et al, *supra* 32 at 167-69.

⁴⁷ *See* 21 U.S.C. 360c (2017), Notes of Decisions “Pre-market approval.”

When considering the requirement for utility as set forth in 35 U.S.C. § 101, courts have previously stated that the utility threshold is not high and “an invention is ‘useful’ under section 101 if it is capable of providing some identifiable benefit.”⁴⁸ In *Brenner v. Manson*, the Supreme Court acknowledged that the concept of utility has maintained a central place in all of our patent legislation beginning with the first patent law in 1790⁴⁹ However, the Court also acknowledged that “[a]s is so often the case, however, a simple, everyday word can be pregnant with ambiguity when applied to the facts of life.”⁵⁰ Such is the essence of the debate regarding “utility” when it comes to implantable, medical devices—specifically in the realm of prosthetic hips.

⁴⁸ *Juicy Whip, Inc., v. Orange Bang, Inc.*, 185 F. 3d 13664, 1366, (USCA, Fed. Cir, 1999).

⁴⁹ *Brenner v. Manson* 383 U.S. 519, 529 (1965).

⁵⁰ *Id.*

The *Brenner* case involved debate about the regarding the utility of a chemical process. There is no doubt that when the Constitutional authors created the “intellectual property clause,” such chemical processes did not exist. One must remember that the tradition regarding patents had strong ties to the concept of increasing aspects of trade.⁵¹ Certainly “machines” or “devices” existed in Colonial America, but there is little doubt that the concepts of such machines and devices had not extended to include implantable prosthetic joints comprised of metal, plastic, and ceramic. As biomedical technology progresses, the courts have faced increasing challenges in determining what patented or patentable inventions fulfill the statutory requirement of being useful. This is readily demonstrated as the courts attempt to address the intellectual property questions involving, for example, the technologies used for testing, delineating, and manipulating human genetic sequences. “Patent protection strikes a delicate balance between creating ‘incentives that lead to creation, invention, and discovery’ and ‘imped[ing] the flow of information that might permit, indeed spur, invention’”⁵²

⁵¹ O. Bracha, *supra* note 25.

⁵² *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.* 569 U. S. 576, 576 (2013) (citing *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* 566 U. S. 66 (2012)).

Modern implantable medical devices can be said to be useful if they are safe, if they achieve their desired clinical result, and if that clinical result is at least as successful as or preferably more successful than currently existing clinical technology. Yet here again, the simple word “safe” is an example of a word “pregnant with ambiguity when applied to the facts of everyday life.”⁵³ Justice Story stated in *Lowell v. Lewis* that “[a]ll that the law requires, is that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society.”⁵⁴

In the realm of orthopaedic prosthetic hip implants, these determinations can be difficult to establish at the time of patent application. Typically patents are applied for and granted after their invention in order to protect the intellectual property of the inventor. However, such patents are granted for devices prior to their evaluation for safety and efficacy by the Food and Drug Administration. In the case of prosthetic total joint implants, once the FDA grants approval for their use, they are released to market and are available for surgical implantation. Inventors, whether they are clinical physicians or implant manufacturing companies, have an interest in obtaining patents to protect their intellectual property and then delivering their products to market as quickly as possible in order to generate revenue to recover their costs for research and development and to please their shareholders.

⁵³ *Brenner*, 383 U. S. at 529.

⁵⁴ *Lowell v. Lewis* 1 Mason 182 Circuit Court, D. Mass 15 F. Cas 1018, 1019 (1817).

In reality, the true evaluation for safety and efficacy begins once these types of medical devices reach the medical marketplace. Patients receiving prosthetic hip implants are counselled by prudent orthopaedic surgeons that their implant is a mechanical device and, like all mechanical devices, can wear out and need to be redone at some point in the future. A total hip patient in the United States could generally expect a ninety percent chance that their total hip would last between ten and fifteen years.⁵⁵

When examining the recent events surrounding certain hip implants, it becomes obvious that certain devices were granted patents that were of questionable usefulness because their safety was suspect due to early clinical failures and due to a need for early revision surgery. Furthermore, when examining the process by which these types of devices were cleared by the FDA, their novelty may also be considered suspect.

IV. FDA Origins and Authority Approval Process

A. Origins and Authority

It is important to understand the origins of Food and Drug Administration when considering the evolution of its relationship with the USPTO. Additionally, this relationship has historically resulted in the regulation of medical devices.

⁵⁵ Jeffrey N. Katz, MD, MSc et al, *Failures of Total Hip Replacement: A Population-Based Perspective*, ORTHO J HARV MED SCHOOL, Vol 9, Manuscripts, 103.

The United States Patent and Trade Office and the Food and Drug Administration share a common heritage dating back to 1848. It was around this time that chemist Lewis Caleb Beck was assigned to the Patent Office to perform chemical testing on agricultural products, and this function was subsequently assumed under the Division of Chemistry and later the Bureau of Chemistry of the United States Department of Agriculture in 1862.⁵⁶ The passage of the Federal Food and Drugs Act, in 1906, “added regulatory functions to the agency’s scientific mission[,]” and was the beginning of the development of the modern Food and Drug Administration which was established by the Federal Food, Drug, and Cosmetic Act of 1938.⁵⁷ The FDA currently operates under the direction of the Department of Health and Human Services.⁵⁸

As part of its function, the Food and Drug Administration has been granted authority to regulate medical devices under the Federal Food, Drug, and Cosmetic Act.⁵⁹ This authority is based in the “constitutional power of Congress to regulate interstate commerce” and to protect the public health “to the end that public health and safety might be advanced.”⁶⁰ Prior to 1976, both pharmaceutical agents and medical devices were regulated together in the same fashion under the auspices of the FDA.

B. The Medical Device Amendments

⁵⁶ U.S. FOOD & DRUG ADMINISTRATION, <https://www.fda.gov/AboutFDA/WhatWeDo/History/> (last visited on Apr. 19, 2018).

⁵⁷ Vincent A. Kleinfeld, *Legislative History of the Federal Food, Drug, and Cosmetic Act*, 50 Food & Drug L.J. 65, 65-100, 1995.

⁵⁸ U.S. FOOD & DRUG ADMINISTRATION, <https://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm> (last visited on Apr. 19, 2018).

⁵⁹ 21 U.S.C. §301, Chapter 9, Subchapter V—Drugs and Devices.

⁶⁰ 21 U.S.C. §301, Note 1 (2017).

In 1976, the Medical Device Amendments (MDA) were adopted to specifically address issues related to the safety, regulation, and marketing of medical devices.⁶¹ In order to address issues specifically related to medical devices, the MDA subdivided various medical devices into three classes. The types and requirements of Class I, Class II, and Class III devices are set forth in 21 U.S.C. § 360c. Surgically implanted hip arthroplasty components are Class III devices as outlined in 21 U.S.C. § 360(c) and are subject to the highest level of FDA regulation.

Since its inception as a one-person department in the USPTO, the FDA has operated under various federal departments to assess the safety of medical devices available to the public. Later, the FDA was granted regulatory authority with ability to classify medical devices and to require manufacturers to demonstrate medical device safety prior to public marketing of such devices.

C. Avenues of Approval for Medical Devices

Since the MDA of 1976, the FDA has allowed medical device approval by one of two pathways: (1) the premarket approval process (PMA); and (2) the 510(k) approval process. The first is a prospective analysis. The second is a retrospective analysis based on “substantial equivalence.”

⁶¹ See Pub. L. 94-295 May 28, 1976; *see also* 21 U.S.C. §360 (2017).

In general, devices that do not fall under Class I or Class II, that are “purported or represented to be for a use in supporting or sustaining human life,” and that “present a potential unreasonable risk of illness or injury” are “subject . . . to premarket approval to provide reasonable assurance of [] safety and effectiveness.”⁶² Class III devices require Premarket Approval whereby a device’s safety is assessed prior to its release to the medical community for use and distribution to the public.⁶³ In addition, new medical devices that seek approval through PMA “require[] an investigational new device (IND) application and a small safety trial The trials are typically randomized, can cost millions of dollars, and can require several years to complete.”⁶⁴ However, an exception is provided for under Section 360(c) when a device had been approved prior to the MDA, and the device is “grandfathered” by a provision allowing pre-1976 devices to remain on the market.⁶⁵

⁶² See 21 U.S.C., § 360(c) (2017): *see also* 21 U.S.C. 360(e) (2017).

⁶³ 21 USC 360c (2017).

⁶⁴ Travis Maak, James Wylie, *Medical Device Regulation: A Comparison of the United States and the European Union*, 24(3), JAAOS, May, 2016.

⁶⁵ *Id.*

In order to “prevent manufacturers of grandfather devices from monopolizing the market while new devices clear PMA,” the FDA allows devices to be approved for use by a separate process known as the 510(k) process.⁶⁶ The 510(k) process does not require clinical testing and reporting of results to the FDA prior to medical device approval for use. Instead, under 510(k) approval, a device is determined to be “substantially equivalent” to a device that had been approved prior to 1976, and consequently such a device may be approved for use without undergoing the more rigorous PMA process.⁶⁷

The ability to obtain 510(k) approval has provided a means by which inventors and developers of hip arthroplasty components may introduce new devices in order to gain access to the 48.1 billion dollar orthopaedic implant device market without having to invest in the more lengthy and expensive clinical trial process prior to FDA approval for use.

The current patent process provides the device developers a means by which they may protect their intellectual property in this potentially lucrative aspect of the medical device market.

As noted above, the 510(k) approval process requires significantly less time than the PMA process. Consequently, inventors will have their intellectual property investment protected for a longer time because patent protection will not have been consumed while waiting for market approval by the FDA. The Court noted in *Medtronic v. Lohr* that the PMA review and the 510(k) notification demonstrate significant time requirements with “1,200 hours necessary to complete a PMA review, [while] the § 510(k) review is completed in an average of only 20 hours.”⁶⁸

⁶⁶ *See supra* note 47

⁶⁷ *Id.*

⁶⁸ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996).

The 510(k) approval process is substantially less expensive to manufacturers. “The mean cost from concept to approval reported in an industry survey was \$31 million for devices approved through the 510(k) process and \$94 million for devices approved through PMA”⁶⁹

In an effort to prevent monopolization and the attendant increase in healthcare cost, Congress passed the Hatch-Waxman Act in 1984.⁷⁰ This effort produced a means by which pharmaceutical manufacturers of generic drugs could “seek approval through establishing bioequivalence to a previously approved pioneer drug.”⁷¹ The Hatch-Waxman Act, however, did not extend an abbreviated approval process to medical devices.⁷² The Act, however, did provide a possibility for patent extension for both new drugs and for new medical devices in order to offset the time of patent protection lost while FDA approval is sought, and this has further been verified by the Supreme Court.⁷³

⁶⁹ See T. Maak, *supra* note 65; see also J. Makeower, A. Meer, L. Denend, *FDA impact on U.S. medical technology innovation: A survey of over 200 medical technology companies*. Washington, DC, Advanced Medical Technology Association, 2010. [HTTP://advamed.org/res.download/30](http://advamed.org/res.download/30).

⁷⁰ Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in sections of 21 U.S.C. and 35 U.S.C.).

⁷¹ Brian P. Wallenfelt, “*Hatch-Waxman and Medical Devices*,” WILLIAM MITCHELL L. REV. 1407, 1415 (2014).

⁷² *Id.* at 1418.

⁷³ See *Id.* at 1419; see also *Eli Lilly v. Medtronic, Inc.* 496 U.S. 661 (1990).

From a public policy perspective, there are two main considerations. First is the interest of the federal government via the FDA in insuring the public release of medical devices with the safest and most efficacious clinical profile to the public. Medical devices that are safe and efficacious—that is, devices that provide utility—will provide for the maintenance and improvement of the public’s health at the least cost to government and to the commercial insurance industry. Devices that are safe and efficacious will likely require the least long term clinical surveillance because their long term safety will have been established. Furthermore, such devices will require the least amount of ongoing medical corrective intervention because the predictability of their long term clinical profile will have demonstrated the least need for future intervention.

Second, the policy of the federal government is to encourage competition to minimize monopolization of the market. Monopolization is likely to result in domination of the medical device market by a few larger manufacturers that have the resources to pursue the more expensive and lengthy PMA process.⁷⁴ In passing the Hatch-Waxman Act, the federal government's desire to encourage competition and decrease cost was codified by facilitating the development of the generic drug market. This particular desire was not, through the Act, extended to the medical device market, although patent extension was extended to medical devices.⁷⁵ As noted in Wallenfelt's article, there is a significant cost differential regarding the development, testing, and manufacture of pharmaceutical agents as compared to medical devices. With pharmacological agents the majority of the expense is related to the research, development, and testing of the agents. Once approval is granted, the actual manufacturing cost represents only a small portion of a company's expense. In contradistinction, medical device manufactures of complex, Class III medical devices, have a significantly larger cost burden with manufacturing the devices. While development and testing—be it via the PMA process or the 510(k) process—can require significant financial investment, ongoing manufacturing costs remain a substantial burden to the manufacturer. This is true whether the manufacturer is the initial developer or is a subsequent generic manufacturer. Consequently, the generic manufacture does not realize as substantial a cost reduction in assuming the production of previously developed and approved devices.⁷⁶

⁷⁴ Wallenfelt, *supra* note 71 at 1422.

⁷⁵ *Id.* at 1422.

⁷⁶ *Id.*

The introduction of the PMA the 510(k) processes was an attempt to balance the FDA's insurance of utilitarian medical devices via established safe and effective clinical profile against the government's and the public's interest in attempting to minimize the cost burden to federal and commercial payers and, eventually, to the public. As subsequent discussion will demonstrate, the outcome of the steps taken can likely be viewed as having the opposite, unintended effects.

D. The Intellectual Property Protection Problem With 510(k) Approval

Two significant issues arise with the patent requirements for novelty and usefulness as applied to medical devices.

As noted above, the first problem inventors face is that temporally, FDA approval is sought after patent application. This creates two problems for inventors and for the USPTO. The first problem is that inventors creating medical devices still are required to obtain FDA approval before their inventions can be released in the marketplace. As previously mentioned, either the PMA process or the 510(k) process are the regulatory avenues that would potentially be utilized for medical devices, and there is no other streamlined mechanism for devices as there is for generic drugs provided by the Hatch-Waxman Act.⁷⁷ When assessing hip implant devices, the PMA process is particularly onerous because PMA requires clinical trials, and clinical trials for hip implants could go on for several years prior to determining the true safety and efficacy of using certain components. Early implant failures detectable in a short survey would not necessarily be related to failure of the function of the prosthetic implants themselves. Rather, early failures would be more likely related to surgical morbidity and mortality—including events such as periprosthetic joint infection, thromboembolic events such as deep venous thrombosis and pulmonary embolism, and postoperative patient death due to comorbid conditions such as coronary and carotid arterial disease. Hip replacement survivability of the implants themselves is typically assessed in short, medium, and long term implant survival which roughly could be divided into two, five, and ten or more years. Occurrences such as excessive bearing wear, host response osteolysis, galvanic trunionosis, and implant loosening from bony fixation may not manifest during the initial year or two of early clinical trial.⁷⁸ All the while during such clinical trials the clock is ticking as to the lifetime of a patent that protects a developer's investment. Patent terms typically are granted for periods of twenty years from the time of patent application.⁷⁹ If PMA is employed and long term studies are utilized, more than half of a patent's life could be consumed before any return on investment is realized by inventors and developers. The Supreme Court noted in *Eli Lilly & Co. v. Medtronic* that “if the discovery relates to a product that cannot be marketed without substantial testing . . . the ‘clock’ on his patent term will be running even though he is not yet able to derive any profit from the invention.”⁸⁰ Even though the Hatch-Waxman Act made provision for extending a patent for medical devices in compensation for time lost awaiting regulatory

approval, the combined period for such extension when combining time awaiting regulatory approval and remaining patent term shall not exceed fourteen years.⁸¹

The second problem is that if the USPTO grants a patent under these circumstances, it does so without truly determining whether a device is useful, because the FDA has not yet deemed it to be safe.

The Patent Office and certain jurisdictions have held that a medical invention, to be patentable, must be shown safe and actually effective by the performance of clinical tests on humans. A second theory, which is now firmly rooted in the Court of Customs and Patent Appeals (CCPA), is that a showing of safety . . . is not necessary to satisfy the statutory requirement⁸²

⁷⁷ See Robert A. Armitage, *The Hatch-Watchman [sic] Act: A Path forward for Making It More Modern* WILLIAM MITCHELL L. REV. 1200-1259 (2014) for discussion of this issue.

⁷⁸ Osteolysis is a condition whereby (whereby a patient develops large cysts in the bone around an implant because of response to microscopic wear particles); galvanic trunionosis is a condition whereby (whereby electromagnetic currents between metal components of differing types cause metallic corrosion)

⁷⁹ 35 U.S.C 154(a)(2) 2017

⁸⁰ *Eli Lilly and Co. v. Medtronic, Inc.* 596 U.S. 661, 669-70 (1990)

⁸¹ 35 U.S.C. § 156(c)(3).

⁸² C. Leon Kim, *The Utility Requirement for Patenting Therapeutic Inventions*, 24 BUFF. L. REV. 595, 612 (1975)

The Supreme Court has previously ruled that “any decision by the FDA on the safety and effectiveness of a new drug is irrelevant to the issue of patentability.”⁸³ Pharmaceutical evaluation, however, evolves differently than evaluation for medical devices in that the majority of drugs do not have cumulative effects, so their safety and efficacy can be more readily evaluated in shorter term clinical trials than the long term surveillance need to assess medical device performance. Other drugs, such as Adriamycin, have dose-dependent effects that are cumulative and require longer terms of assessment similar to the evaluation of medical devices.⁸⁴ Furthermore, these types of judicial decisions were made primarily related to the use of pharmaceutical agents. They were made at a time before the widespread implantation of prosthetic joint implants in large segments of the population. The Supreme Court’s opinion in *Brenner* was decided in 1965, at a time when total hip replacement was in its earliest stages of development. In 2010, 310,000 total hip replacement procedures were performed, and it is estimated that there are approximately 2.5 million implanted total hip replacements in the United States.⁸⁵

The second problematic consideration is how the 510(k) approval process relates to the novelty requirement of patents embodied in 18 U.S.C. § 102. The 510(k) approval process is employed to bypass the FDA’s PMA requirement. When applying for 510(k) approval, a device is claimed to be “substantially equivalent” to a device previously approved by the FDA.

⁸³ *Id.* at 596; *see Brenner v. Manson*, 383 U.S. 519 (1966); *see also* Application of Hartop 311 F. 2d 249, 257 (C.C.P.A 1962).

⁸⁴ Adriamycin is a chemotherapy agent that may be used for treatment of breast cancer.

⁸⁵ Maradit Kremers, et al, *Prevalence of Total Hip and Knee Replacement in the United States*, J BONE JOINT SURG AM, 2015 Sep 2, 97(17), 1386-97.

This generates two issues for consideration. First, if a device is substantially equivalent, then does it truly fulfill the novelty requirement of § 102? Perhaps one needs to look to third statutory requirement introduced by the Patent Act of 1952 to establish patentability—the requirement of non-obviousness.⁸⁶ The non-obvious subject matter requirement specifically states that “if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed inventions pertains.”⁸⁷ The requirements of utility, set forth in § 101, and novelty, set forth in § 102, have been longstanding elements of patentability dating back to the passage of the Patent Act of 1790. However, the concept of novelty was further delineated with the addition of the requirement of non-obvious subject matter. Though non-obviousness was codified in 1952, there is a long judicial history of the application of the Hotchkiss test stemming from the 1851 Supreme Court decision in *Hotchkiss v. Greenwood*, 11 How. 248, 13 L. Ed. 683.⁸⁸

⁸⁶ The current variation is found in 35 U.S.C. § 103 (2011).

⁸⁷ 35 U.S. C. § 103 (2011).

⁸⁸ *See* *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 684, 687-695 (1966) for J. Clark’s discussion of the evolution of this judicial precedent and its eventual embodiment in the Patent Act of 1952.

The Hotchkiss test informally established in 1851 states that “unless more ingenuity and skill . . . were required . . . than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that skill and ingenuity which constitute essential elements of every invention.”⁸⁹ The non-obviousness requirement, then, further delineates the novelty requirement such that “[a]n invention which has been made, and which is new in the sense that the same thing has not been made before, may still not be patentable”⁹⁰

⁸⁹ *See Id.* at 684, 690; *see also* *Hotchkiss v. Greenwood*, 11 How. 248, 267, 13 L. Ed. 683.

⁹⁰ *Graham*, at 692.

The result of the current scheme is that implant manufacturers are currently designing and seeking patents for new variations of total hip implants claiming they are useful, fulfilling the § 101 requirement, novel, fulfilling the § 102 requirement, and non-obvious, fulfilling the § 103 requirement. The manufacturers are then taking their patented designs to the FDA and pursuing 510(k) approval based on arguments of substantial equivalence. They are claiming that the newly designed or modified implants are similar enough to those previously approved and consequently should be granted FDA 510(k) approval. This is all done with the intention of protecting the intellectual property investment in time and in capital with the limited monopoly of a patent, but avoiding the time, expense, and prolonged consumption of patent protection by the onerous PMA approval process.

Historically, substantially equivalent devices have been approved by the FDA based on devices that were previously approved. However, there are instances where medical devices have been subsequently voluntarily withdrawn or voluntarily recalled by manufacturers because of poor clinical performance of the devices or because of safety concerns. The quintessential example of this is the recent activity surrounding the ASR metal-on-metal hip manufactured by DePuy.⁹¹ The ASR hip was approved for sale in the United States by the FDA in July, 2008 based on a 510(k) clearance application. This application was based, among others, on U. S. Patent No. US 5904720 A.⁹² In September, 2008, the Australian Orthopaedic Association National Joint Replacement Registry was reporting that this device had a significantly higher than expected revision rate.⁹³ DePuy recalled the device voluntarily in 2009 in Australia for “declining demand.”⁹⁴ The National Joint Registry of England and Wales reported in 2010 that the five-year revision rate for this device was five times higher than for all other devices combined at thirteen percent, and as a result of the data from England and Wales, DePuy completely withdrew the product from the world market in 2010.

⁹¹ See Brent M. Ardaugh, et. al. *The 510(k) Ancestry of a Metal-on-Metal Hip Implant*, N ENGL J MED 368:2, pp 97-100, Jan 10, 2013.

It is a quirk of law that allows devices to be evaluated for 510(k) approval by the FDA, as long as the substantially equivalent predicates have not been withdrawn from the market because of court order or because of FDA directed recall.⁹⁵

Inherent in the nature of the 510(k) approval process for these various metal-on metal hip implants is the introduction of the issue referred to as “predicate creep.” Predicate creep can readily occur during the 510(k) process when each new device is changed slightly as compared to its previously approved predicate substantial equivalent. As each new substantially equivalent device is slightly altered and submitted for approval, the result can be, after several permutations, that the current device submitted as a substantial equivalent bears little resemblance to the original parent device. This is precisely the problem demonstrated in the current generation of metal-on-metal hip arthroplasties.⁹⁶

⁹² See *supra* note 63.

⁹³ Ardaugh, *supra* note 90.

⁹⁴ *Id.* at 98.

⁹⁵ Institute of Medicine, *Medical devices and the public's health: the FDA 510(k) clearance process at 35 years*, Washington DC: National Academies Press, 2011.

⁹⁶ See Arianne Freeman, *Predicate Creep: The Danger of Multiple Predicate Devices*, 23 ANNALS HEALTH L. ADVANCE DIRECTIVE 127, 2014.

In a 2014 article, Arianne Freeman actually advocates for complete elimination of the 510(k) approval process, arguing that the process “shifts device testing from the clinical trial setting to the public market place, thus unethically veering potential risks to the patients.”⁹⁷ In fact, “Congress had always intended class III devices to undergo PMA, and in 1990, it directed the [FDA] to establish a schedule to finish the transition to PMAS for all devices that were to remain in class III,” but the FDA had, as of December 2012, not completed the transition requested by Congress.⁹⁸

In more recent developments, however, the FDA has instructed prosthetic hip manufacturers that they must seek premarket approval for metal-on-metal hip components with acetabular components held to the bone either by bone cement or held in press-fit fashion. This order went into effect in February, 2016.⁹⁹

Congress and the FDA have indicated that there is an increasing desire to eliminate the 510(k) approval process because of the inherent problems discussed above regarding substantial equivalence and the potential development of predicate creep.¹⁰⁰ What has not been addressed, however, is the disconnect created by granting a patent based on utility, novelty, and non-obviousness to a medical device that is subsequently submitted for FDA approval based on substantial equivalence to a predicate device.

V. Economic Impact of ASR Hip Recalls

⁹⁷ *Id.*; see Deborah Cohen, *How safe are metal-on-metal hip implants?*, 1(4) BRIT. MED. J., Feb. 28, 2012, <http://www.bm.com/content/344/bmj.e1410.pdf%2Bhtml> [hereinafter *How safe are metal-on-metal hip implants?*].

⁹⁸ See Ardaugh, *supra* note 90; see also Freeman, *supra* note 95.

⁹⁹ U. S. FOOD & DRUG ADMINISTRATION, <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedure/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241769.htm> (last visited on Apr. 19, 2018).

¹⁰⁰ *Id.*; see also Freeman, *supra* note 95.

The voluntary recalls of the ASR hip by DePuy and of other metal-on-metal hips has resulted in extended product liability litigation and an enormous economic burden to society and to the medical device manufacturing community. The large numbers of product liability related lawsuits have placed a large burden on the United States judicial system.

As a result of the clinical failures of the ASR hip and the subsequent voluntary recalls by Johnson & Johnson, DePuy's parent company, multiple product liability lawsuits were filed. Many of the plaintiffs' cases have been consolidated either into multidistrict litigation or into class action lawsuits.¹⁰¹ Furthermore, a search on one of the online legal services for "DePuy ASR" will result in multiple citations for various pending or resolved actions across the country. While the actual number of plaintiffs is difficult to ascertain, approximately 10,000 individuals in two different settlements will recover just over four billion dollars.¹⁰² While this is an estimated settlement cost to DePuy, this figure does not take into account the other millions of dollars spent across the country in pursuit of these legal actions. Furthermore, it does not take into consideration the countless hours of time spent by attorneys for both sides, judges and their staffs, and the actions required by the various plaintiffs and defendant representatives. The actual expenses including various lost wages and pain and suffering costs could extend into the tens of billions of dollars.

¹⁰¹ See, eg. 13 No. 8 Westlaw Journal Nursing Home 8, October 8, 2010, California Man Files Class Suit Over Recalled Depuy Hip Implants; see also, eg U.S. Judicial Panel on Multidistrict Litigation, MDL Statistics Report-Distribution of Pending MDL Dockets by District (Sept. 16, 2017) http://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-September-15-2017.pdf.

¹⁰² Barry Meier, *Maker Aware of 40% Failure in Hip Implant*, N.Y. TIMES (Jan. 22, 2013), <http://www.nytimes.com/2013/01/23/business/jj-study-suggested-hip-device-could-fail-in-thousands-more.html>; see also Jef Feeley and David Voreacos, *J & J Said to Reach \$4 Billion Deal to Settle Hip Lawsuits*, BLOOMBERG (Nov. 13, 2013), <https://www.bloomberg.com/news/articles/2013-11-12/j-j-said-to-reach-4-billion-deal-to-settle-hip-lawsuits>.

One must remember that the ASR hip recall and its resultant litigation was only one of several recalls involving either different manufacturers, such as Stryker or Zimmer, or other product lines belonging to DePuy, such as the Pinnacle hip which is also manufactured by DePuy. The Minneapolis Star Tribune reported that Stryker had reached a \$1.4 billion settlement in a separate but related lawsuit involving a different type of metal-on-metal articulation between the femoral stem and the femoral neck of hip implants.¹⁰³

While hip implant manufacturers may have been able to decrease costs by pursuing 510(k) approval instead of PMA approval, it would appear that the rush to get implants to market for competition purposes has resulted in a substantially larger cost to the manufacturers than would have otherwise been realized. Furthermore, the actions of the device manufacturers effectively created a large unmonitored clinical trial that shifted the burden and the risk to the population of individuals requiring a total hip arthroplasty.

VI. Public Policy Considerations

Given the unfortunate events surrounding this regulation, implantation, and subsequent recall of the DePuy's ASR hip, the natural inclination and visceral response would be to try to effect changes that would prevent a similar occurrence in the future. This is, perhaps, more easily suggested than accomplished.

The Constitutional history of the United States and the legislative history of Congress have confirmed that the protection of intellectual property rights via Article I, Section 8, Clause 8, as well as the availability of transient, limited monopolies through the patent process, enumerated in the most recent America Invents Act, will be preserved. If inventors and scientists and industry are disincentivized to be innovative, then it is likely that progress in medical device development will diminish.

¹⁰³ Joe Carlson, *\$1.4 billion settlement announced in artificial hip litigation*, STAR TRIBUNE (Dec. 14, 2014), <http://www.startribune.com/nov-3-1-4-billion-settlement-in-artificial-hip-litigation/281375461/>.

That being said, some form of regulation and safety assessment still needs to be performed whether by a governmental agency such as the FDA or by some other private entity to ensure that medical devices that are made available to the public are safe and effective. No regulatory scheme will be able to prevent mechanical failures of medically implanted prosthetic devices such as total hip arthroplasty components. As a result of the events involving the ASR and other metal-on-metal hips, the FDA has abolished the 510(k) mechanism and mandated PMA evaluation for certain types of hips with metal-on-metal bearings.¹⁰⁴ While this action may result in more thorough, short term clinical evaluation with the potential for increased safety for the public, it is likely to have two other effects. First it is likely to deter scientists and manufacturers involved in the development of prosthetic hips from pursuing research along these lines—especially when considering the price tag of the evolving litigation relating to such implants. Second, should scientists and developers pursue this “useful art”, the costs of research, regulatory approval and defense against potential litigation are likely to prove to be significantly more, if not prohibitively expensive. As is true in the nature of business transactions, this will result in the cost being passed along to the consumer, be it to the individual patient or to a corporate consumer such as a health care system or the federal government.

¹⁰⁴ *See supra* note 100.

It is a knee-jerk response to suggest that previously developed and marketed technologies that have fallen by the wayside due to suboptimal performance should be altogether abandoned. The history of total joint arthroplasty specifically, and or orthopaedic surgery in general is comprised of similar procedures or technology that were not initially successful, were buried in the archives of history, and were subsequently resurrected in new, modified, more successful versions. For example, THA was previously associated with a disturbingly high infection rate as well as an unacceptable rate of hip instability, whereby the hip would dislocate from the socket after surgery. Multiple aspects of the procedure are notable for its success, but progressive technological developments have all contributed to the extreme success of the operation¹⁰⁵—so much so that it was dubbed the “operation of the century.”¹⁰⁶ If some of the regulatory processes had been made more stringent, and if some of the intellectual property protective benefits had been eliminated, it is unlikely that the success of the operation would have developed and advanced as much as it has in the last fifty years.

VII. Possible Solutions to the Conundrum

Unravelling this spiderweb of overlapping regulation, unintended consequences, and seemingly conflicting purposes is not easy. There are, however, some solutions to propose.

¹⁰⁵ Important developments in THA include use of perioperative antibiotics, use of laminar flow operating rooms with special air handling characteristics, shorter operative times, smaller, less invasive incisions, and implant modification involving less invasive implants with more physiologically sized femoral heads.

¹⁰⁶ I.D. Learmonth ID, C. Young, C. Rorabeck, *The Operation of the Century: Total Hip Replacement*, 370(9597) LANCET, Oct. 27, 2007 7:370(9597): 1508-19.

While monopolies have been distasteful—both to our English legal ancestors as manifested in the no Monopolies act, and to the Patent Office from its earliest days with Thomas Jefferson,¹⁰⁷ it may be necessary to extend the length of patent protection. Justice Story commented in *Graham* in 1966 “Technology [] has advanced—and with remarkable rapidity in the last fifty years. Moreover, the ambit of applicable art in given fields of science has widened by disciplines unheard of half a century ago.”¹⁰⁸ Perhaps this advent of these new and previously unheard of technologies will necessitate an overhauling of the patent system more equipped to handle the complexities of this previously unheard of applicable art.

One possibility would be to develop a tiered patent system that grants patents of varying lengths—for example twenty, thirty-five, and fifty years—to accommodate the complexity of obtaining more thorough regulatory evaluation and testing.

Another option would be to develop patent tracts for the various classes of medical devices such that items in Class I are evaluated for patents in a different fashion or with different criteria than Class III medical devices, which would be evaluated with a different set of criteria or different time frame.

Another way to manage this would be to delay the patent process or modify it until after the regulatory evaluation is completed. Pre-patent protection could still be provided by an application process that provides public notice to the scientific and manufacturing communities that prior art has been established. The potential limitation to this is that inventors and manufacturers are unlikely to invest the larger sums of money that will be required of product research, development and testing without the assurance that their intellectual property would be protected.

¹⁰⁷ See Halpern, *supra* note 32; see also *Graham v. John Deere Co. of Kansas City*, 383 U. S. 1, 684, 688 where J. Clark noted “Jefferson, like other Americans, had an instinctive aversion to monopolies.”

¹⁰⁸ *Graham* at 694.

The USPTO could review and grant patents that have fulfilled the requirements of utility, novelty, and non-obvious subject matter, but the lifetime of the patent could only be counted upon the technology's completion of its regulatory approval process.

One way to solve the seeming conflict between requiring safety to fulfill the usefulness criteria of § 102 is to pursue a regulatory process similar to that currently in use in Europe. The European equivalence of the FDA's PMA process is the CE mark (Conformite Europeenne) which allows a medical device to be marketed in all European countries.¹⁰⁹ The CE mark requires proof of the device's performance, whereas US FDA approval of a PMA application requires proof of the device's safety and efficacy.¹¹⁰ This would avoid the perceived conflict of requiring the establishment of safety to provide for utility and would be in conformity with the Supreme Court's decision in *Brenner*. One caveat is that given some of the recent high-profile device failures in the European Union, the European Union appears to be moving more toward a regulatory system reflecting that provided by the FDA.¹¹¹

¹⁰⁹ T. Maak, J. Wylie, *supra* note 65.

¹¹⁰ *Id.*; DB Kramer, S Xu, and AS Kesselheim, *Regulation of Medical Devices in the United States and European Union*, N ENGL J MED 2012: 366(9): 848-855.

¹¹¹ D. Kramer, et. al. *supra* note 109.

Yet another means of resolving this perceived conflict would be for developers of medical devices to abandon pursuing patent protection of their intellectual property. Instead, they could pursue trade secret protection. “An innovator might choose to protect information or an invention via trade secret instead of patent law because a trade secret holder will never have to disclose the information ‘as long as the information remains secret and meets other judicial criteria allowing for the preservation of its secrecy.’”¹¹² Because there is no defined longevity of trade secret effectiveness, the length of time for FDA PMA approval would not be as restrictive to the potential lucrativeness of developing medical devices requiring long clinical trials. The downside to this proposal is the resulting introduction of another entirely separate statutory scheme under the Economic Espionage Act and the associated Defend Trade Secrets Act.¹¹³

A somewhat “Modest Proposal”¹¹⁴ would be to either eliminate the function of the USPTO patentability requirements or the FDA’s watchdog function. While this may give cause for great rejoicing among some members of the medical community, they would still have to admit begrudgingly that the FDA serves an essential function in safeguarding the health of U.S. citizens.

¹¹² Robin J Effron, *Trade Secrets, Extraterritoriality, and Jurisdiction*, 51 WAKE FOREST L. REV. 765, 767, (Fall 2016); and Robin J. Effron, *Secrets and Spies: Extraterritorial Application of the Economic Espionage Act and the TRIIPS Agreement*, 78 N.Y.U. L. REV. 1475, 1476-77 (2003).

¹¹³ 18 U.S.C §§ 1831 and 1839 (1996).

¹¹⁴ Jonathan Swift, *A Modest Proposal: For Preventing The Children of Poor People in Ireland From Being a Burden to Their Parents or Country, and For Making Them Beneficial to the Public*, (1729).

Perhaps the best solution involves a two-pronged change to the regulation of these types of implantable devices and their associated protection as intellectual property under patent law. First, the FDA should subdivide Class III devices into, say, Class IIIA and Class IIIB devices and require all Class III devices to undergo PMA. Class IIIA would be those devices that can have their clinical safety established relatively quickly under PMA—within, say, twenty-four months. Class IIIB would be those devices that take longer than twenty-four months to establish clinical safety by pre-market analysis.

The current patent structure would remain the same for Class IIIA devices. However, for Class IIIB devices, the patent structure could be modified such that the patent is applied for with the initiation of the pre-market analysis for the device, but the actual granting of the twenty-year patent protection occurs only upon completion of pre-market analysis be it at two, five, or however many years.

There are several benefits to this proposal. First, the clinical devices that require a longer time to establish clinical safety, and therefore usefulness, would all undergo PMA rather than 510(k) FDA approval. Second, inventors would be assured their inventions would receive patent protection for a full twenty years. Finally, from a public policy perspective, patients could be assured that the implants with which they are treated have undergone the more rigorous PMA establishment of clinical safety, and the nation and economy would benefit by encouraging designers to pursue the development of such implants for the benefit of the populace with the knowledge that their intellectual property would be protected for the full patent term.

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