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The Experimental Use Exception and Undergraduate Engineering Projects

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THE EXPERIMENTAL USE EXCEPTION AND UNDERGRADUATE ENGINEERING PROJECTS

INTRODUCTION

Following four long years of higher education, Joe Engineering Student is looking forward to graduation and reaping the benefits of his education. After countless hours spent reading textbooks, answering homework problems, studying for and taking exams, and working on laboratory projects, Joe is finally ready to take his proud stroll across the graduation stage. He is especially proud of the fine work he and his partners have done on their capstone senior design project over the past nine months. Joe is, in fact, so proud of his team's fine engineering work that he has included a brief description of the project on the resume he has been using during his search for employment, and his team has taken the time to chronicle their efforts using a web page.[1] It is only a matter of days before Joe and his partners will be giving their final presentations to the rest of their classmates and taking part in the annual senior design show. Joe has been looking forward to this day because not only will it represent the culmination of this hard-won education, but he will also have the opportunity to show off the project to his fiancé and the rest of his family. On this day, like many others, he stops by his mailbox on the way to class. Within the mailbox he finds a letter from Brown & Smith. Joe cannot recall sending a copy of his resume to an engineering firm by that name, but he opens it immediately thinking it might include a job offer. His hopes are quickly dashed. Brown & Smith have sent Joe, and the rest of his project teammates, a cease and desist letter. According to Brown & Smith, Joe's project appears to infringe upon one or more of their client's patents. The letter further informs Joe that failure to immediately cease the infringing activity makes him liable for treble damages. What is Joe to do? If he heeds the letter, then he cannot present his project. If he does not present his project, then he cannot graduate. And there simply is not time to figure out how the project may be infringing upon the indicated patents, much less re-engineer the project so that it is no longer infringing. What can Joe do?

After panicking, Joe calms down and calls his aunt, an intellectual property attorney. His aunt explains to him the unlikelihood that he and his team will, in fact, be sued for this alleged infringing use.[2] While

1. The use of web pages to document and publicize capstone senior design projects is becoming rather commonplace. *See*, *e.g.*, Stored Tagging File Utility (Tag), http://jade.msoe.edu/tag/ (last visited Feb. 20, 2008).

2. Aside from the obvious possibility that the project is not even infringing, there are additional reasons that Joe is unlikely to be sued. Given the extreme expense of a patent infringement suit and the unlikelihood of showing, much less obtaining, significant damages

this may be of some comfort to Joe, it really does not help Joe answer the real question regarding his legal options should he and his team be found to be infringing. Assuming, *arguendo*, that Joe's project does infringe some of these patents, what substantive legal advice can be given to Joe?

In general, U.S. patent law provides a patent holder only with negative rights with respect to a patent.[3] More specifically, the United States Code describes infringement as any unauthorized activity that "makes, uses, offers to sell, or sells any patented invention."[4] The Code does not make any specific provision that the intent of the infringer is a factor in any analysis of infringement.[5] Nevertheless, there is a long tradition of a judicially created exception to this rule, referred to as the "experimental use exception."[6] The Circuit Court of Appeals for the Federal Circuit [hereinafter Federal Circuit], in its recent decisions in *Madey v. Duke University*[7] and *Integra Lifesciences I, Ltd. v. Merck KGaA*,[8] has very narrowly interpreted the extent of the experimental use exception.[9] There has been much commentary on the effect these

from Joe, the suit may not be practical. *See* Elizabeth A. Rowe, *The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?*, 57 HASTINGS L.J. 921, 943 (2006). There may be a possibility of suing the professor who advised the project or Joe's university under a contributory or vicarious infringement theory, which would deepen the pockets, but that is an issue beyond the scope of this Comment. In addition, industry has shown a strong reluctance to sue universities over patent infringement in a model that has been characterized as "rational forbearance" because industry has more to lose than it might gain over such a lawsuit. Michelle Cai, Madey v. Duke University*: Shattering the Myth of Universities' Experimental Use Defense*, 19 BERKELEY TECH. L.J. 175, 185-86 (2004). Studies have shown that very few academic research projects have been abandoned due to infringement on third-party patents. Michael S. Mireles, Jr., *States as Innovation System Laboratories: California, Patents, and Stem Cell Technology*, 28 CARDOZO L. REV. 1133, 1165 (2006).

3. 35 U.S.C. § 271(a) (2006).

4. *Id.*

5. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 36 (1997).

6. R. CARL MOY, 2 MOY'S WALKER ON PATENTS § 8:246 (4th ed. 2006). There are actually two "experimental use exceptions" commonly applied to patent law. The first exception applies to the experimental use of an invention prior to filing a patent application that tolls the one-year limit on prior public use of the patented subject matter. 35 U.S.C. § 102(b) (2006); MOY § 8:246. The second exception provides, as a defense, that under certain circumstances a patented invention may be used without authorization. *Madey v. Duke University*, 307 F.3d 1351, 1360 (Fed. Cir. 2002). This second exception is the sole basis for this Comment. A more detailed description of this defense will be presented *infra* Part II.

7. 307 F.3d 1351 (Fed. Cir. 2002).

8. 331 F.3d 860 (Fed. Cir. 2003) (2-1 decision), *vacated*, 545 U.S. 193 (2005). The Supreme Court has very broadly interpreted the experimental use exception under the "FDA Safe Harbor" of 35 U.S.C. § 271(e). *See infra* Part II.C.

9. *See infra* Part II.

decisions will have on the university research community, but so far no one has substantively addressed the experimental use exception in the context of undergraduate education and, more specifically, how the exception might be applied to capstone senior design projects. This Comment will address this issue and explain how the exception is likely to be applied to capstone senior design projects.

Part I of this Comment will describe the characteristics of typical capstone senior design projects. They will be compared with the graduate research programs that are generally addressed by other commentary on the experimental use exception, and the relevant elements of these undergraduate projects will be identified. Part II of this Comment will review the history and evolution of the experimental use exception to identify the rationale and criteria under which the Federal Circuit is basing its decisions. The experimental use exception will then be applied to capstone senior design projects to determine if and when it is available as a defense to infringement in Part III. The results of this analysis will then be summarized in Part IV.

I. CAPSTONE SENIOR DESIGN PROJECTS

Undergraduate engineering education in the United States is driven by a number of complex, interweaving concerns and demands. Chief among these concerns is that a university with an engineering degree program is expected, in a relatively short four-year period, to transform a high school graduate with a strong mathematics or science background and little or no knowledge of either engineering or engineering principles, into a work-ready graduate who is prepared to practice engineering upon graduation. In fact, engineering is one of the few professions that provides the bulk of its formal training at the undergraduate level,[10] with most other professions requiring additional years of graduate school training.[11]

10. While most of an engineer's formal training does occur in the undergraduate classroom and laboratory, it, by itself, is insufficient to obtain licensure as a "Professional Engineer." *See, e.g.,* WIS. STAT. § 443.04 (2005-06). The rules for licensure as a "Professional Engineer" vary somewhat from state to state, but the typical requirement is a degree from an accredited four-year engineering degree program, two eight-hour exams, and four years of supervision under another engineer. *See, e.g.,* WIS. STAT. §§ 443.04, 443.09 (2005-06). Surprisingly enough, the vast majority of engineering graduates do not seek professional licensure, as most engineering projects either do not require supervision by a licensed professional engineer or it is considered sufficient that only one licensed professional engineer is required to supervise a project. *See, e.g.,* http://www.memagazine.org/backissues/membersonly/may99/features/tolicense/tolicense.html. (last visited Feb. 20, 2008). This is quite different from most other professions, where licensure is generally a prerequisite to

Colleges and universities in the United States graduate over 73,000 engineers each year.[12] As is natural among all professions, both prospective engineering students and the industries hiring those graduates would like some assurances that the engineering education being provided meets certain standards for quality and thoroughness. To satisfy this requirement, the vast majority of engineering programs in the United States voluntarily participate in an accreditation process coordinated by the Accreditation Board for Engineering and Technology ("ABET").[13] To achieve this lofty goal, ABET promulgates a series of accreditation criteria that programs must meet to satisfy the accreditation process.[14] A common requirement among all engineering programs is a "major design experience,"[15] which most engineering degree programs incorporate into their curricula as a capstone senior design project. The following Sections will further examine the capstone senior design project by describing the ABET accreditation process, looking at the characteristics of some common types of capstone senior design projects, and then comparing the capstone senior design project to graduate research.

A. The Accreditation Board for Engineering and Technology

ABET is the recognized accreditation agency for degree programs in engineering, computing, applied science, and technology.[16] Its primary responsibility is to ensure that the graduates of these degree programs

professional practice. *See, e.g.,* U.S. Department of Labor, Lawyers, http://www.bls.gov/oco/ocos053.htm (last visited Feb. 21, 2008); U.S. Department of Labor, Physicians and Surgeons, http://www.bls.gov/oco/ocos074.htm (last visited Feb. 21, 2008).

11. Lawyers and doctors, for example, are required to complete extensive coursework and degrees beyond the undergraduate level. *See* U.S. Department of Labor, Lawyers, *supra* note 10; U.S. Department of Labor, Physicians and Surgeons, *supra* note 10.

12. In 2005, 73,602 bachelor's degrees were awarded in engineering. Thomas K. Grose, *Trouble on the Horizon,* ASEE PRISM, Oct. 2006, at 27. This is expected to stay relatively unchanged in the near future because freshman enrollment in engineering has been nearly stable over the past four years. *Id*. at 28.

13. ABET "accredits programs only, not degrees, departments, colleges, or institutions." ABET: The Basics, What is ABET Accreditation?, http://www.abet.org/the_basics.shtml (last visited Apr. 2, 2008). For example, ABET might accredit a computer engineering degree program at a particular university. *Id.* For more information on ABET and its accreditation processes and criteria, see *infra* Part I.A.

14. *See infra* Part I.A.

15. ABET Board of Directors, *Criteria for Accrediting Engineering Programs: Effective for Evaluations during the 2007-2008Accreditation Cycle* 3 (Mar. 17, 2007), *available at* http://www.abet.org/Linked%20Documents-UPDATE/Criteria%20and%20PP/E001%2007-08%20EAC%20Criteria%2011-15-06.pdf [hereinafter *Criteria 2000*].

16. Overview of ABET, http://www.abet.org/overview.shtml (last visited Apr. 2, 2008).

have received a quality education.[17] ABET was founded in 1932, and it is comprised of a federation of twenty-eight technical and professional societies covering the broad range of degree programs it accredits.[18] Using, primarily, a labor force of more than 1500 volunteers, ABET accredits approximately 2700 degree programs at over 550 colleges and universities across the United States.[19] During the 2004-2005 academic year, ABET was responsible for accreditation activities that affected 664 degree programs across the country.[20]

Over the years, ABET has promulgated a series of criteria for the various programs it is responsible for accrediting. Because ABET believes that each of the technical specialties is in the best position to determine which criteria should be applicable to specific degree programs, it has divided the accreditation criteria into two components: general criteria applicable to all accredited programs and program criteria applicable to various degree programs based upon the name of the degree granted.[21] To accomplish this goal, ABET has divided itself into four accreditation commissions with each responsible for one of ABET's four main areas.[22] Most engineering degree programs fall under the responsibility of the Engineering Accreditation Commission (EAC).[23] The last major revision to the engineering accreditation guidelines was developed at the end of the twentieth century and is colloquially referred to as "Criteria 2000."[24] Since its adoption in the late 1990s, Criteria 2000 has undergone a series of regular revisions.[25]

17. *Id.*

18. *Id.*

19. *Id.*

20. Accreditation Statistics: 2004-2005 Cycle Data (2005), *available at* http://www.abet.org/Linked%20Documents-UPDATE/Stats/05-AR%20Stats.pdf.

21. *See Information for Programs Seeking Initial Accreditation*, *available at* http://www.abet.org/Linked%20Documents-UPDATE/Program%20Docs/New%20Program%20FAQ.pdf [hereinafter *Information for Programs*]. ABET refers to this as "truth in advertising." Kathryn B. Aberle, *Selecting an Engineering Course in the United States*, http://www.science-engineering.net/america/selecting_engineering_course.htm (last visited Apr. 10, 2008).

22. *Information for Programs*, *supra* note 21

23. *Id.* There are a few engineering programs that also fall under other ABET commissions. For example, both computer engineering and software engineering are accredited jointly with the Computing Accreditation Commission (CAC) and the Computer Science Accreditation Board (CSAB). *See* Criteria 2000, *supra* note 15, at 10, 18.

24. *See* Accreditation Director, ABET, Engineering Criteria 2000, 3d Ed. (June 29, 1998), http://www.ele.uri.edu/faculty/daly/criteria.2000.html.

25. *See* Criteria 2000, *supra* note 15, at 19-24.

Engineering degree programs subject to accreditation under Criteria 2000 must satisfy eight general criteria[26] in addition to criteria specific to the degree program.[27] While each of the eight criteria are of equal importance, the most comprehensive and time consuming to evaluate is Criterion 3.[28] Criterion 3 identifies eleven specific abilities that engineering students must demonstrate upon graduation and serves as a general description of the abilities that an engineer will need to practice successfully during her career. These include, among others, the ability to apply mathematics and science, design complex systems subject to realistic constraints, work on multi-disciplinary teams, and the ability to apply skills and tools to engineering practice.[29] Due to the broad nature

26. *Id.* at 1-3. These criteria examine students, program educational objectives, program outcomes and assessment, professional components, faculty, facilities, institutional support and financial resources, and program criteria. *Id.*

27. The program criteria are referenced generally as General Criterion 3. *Id.* at 3. Each individual degree program type, however, has its own additional criteria that are promulgated in conjunction with one or more technical societies. For example, electrical engineering and other similarly named degree programs receive their program-specific criteria, in part, from input received from the Institute of Electrical and Electronics Engineers (IEEE). *Id.* at 10. The IEEE styles itself as "[t]he world's leading professional association for the advancement of technology" and is the premier technical society for a wide range of technical fields loosely associated with electrical engineering. About the IEEE, http://ieee.org/web/aboutus/home/index.html (last visited Feb. 22, 2008).

28. *See* Criteria 2000, *supra* note 15, at 1-2.

29. *Id.* at 2. These are often referred to as ABET 3(a)-(k). The full text of Criterion 3 states:

> Although institutions may use different terminology, for purposes of Criterion 3, program outcomes are statements that describe what students are expected to know and be able to do by the time of graduation. These relate to the skills, knowledge, and behaviors that student [sic] acquire in their matriculation through the program.
>
> Each program must formulate program outcomes that foster attainment of the program objectives articulated in satisfaction of Criterion 2 of these criteria. There must be processes to produce these outcomes and an assessment process, with documented results, that demonstrates that these program outcomes are being measured and indicates the degree to which the outcomes are achieved. There must be evidence that the results of this assessment process are applied to the further development of the program.
>
> Engineering programs must demonstrate that their students attain:
>
> a) an ability to apply knowledge of mathematics, science, and engineering
> b) an ability to design and conduct experiments, as well as to analyze and interpret data
> c) an ability to design a system, component, or process to meet desired needs within realistic constraints such as economic, environmental, social, political, ethical, health and safety, manufacturability, and sustainability
> d) an ability to function on multi-disciplinary teams
> e) an ability to identify, formulate, and solve engineering problems
> f) an understanding of professional and ethical responsibility

of Criterion 3, all the abilities listed there are rarely addressed by a single classroom or laboratory assignment in an engineering degree program. To further aid engineering degree programs in determining an appropriate curriculum, Criterion 4 contains a series of minimum credit hour requirements.[30] Included within Criterion 4 is the requirement that "[s]tudents must be prepared for engineering practice through the curriculum culminating in a major design experience based on the knowledge and skills acquired in earlier coursework and incorporating appropriate engineering standards and multiple realistic constraints."[31] ABET has, in effect, with this criterion mandated that all engineering degree programs include some type of capstone senior design project.

Because the ABET accreditation criteria are descriptive rather than prescriptive, engineering degree programs are given wide flexibility in determining how they satisfy each of the criteria.[32] Engineering degree programs have exercised great creativity in developing a broad range of exercises and activities that satisfy the major design experience. The following Section will provide some insight into how some typical capstone senior design projects satisfy the major design experience requirement.

B. Exemplary Capstone Senior Design Projects

In response to the ABET mandate for incorporation of a major design experience into all engineering degree programs, the faculty at colleges and universities across the United States have developed a broad range of pedagogical exercises designed to satisfy this accreditation requirement. For most engineering degree programs, this

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g) an ability to communicate effectively
h) the broad education necessary to understand the impact of engineering solutions in a global, economic, environmental, and societal context
i) a recognition of the need for, and an ability to, engage in life-long learning
j) a knowledge of contemporary issues
k) an ability to use the techniques, skills, and modern engineering tools necessary for engineering practice.

In addition, an engineering program must demonstrate that its students attain any additional outcomes articulated by the program to foster achievement of its education objectives.

Id. at 1-2.

30. *Id.* at 2-3. These are referred to as the "Professional Component" of a degree program. *Id.*

31. *Id.* at 3.

32. Criteria 2000, *supra* note 15, at 2.

requirement is satisfied through the incorporation of a series of courses in the various curricula generally referred to as capstone senior design. The number and variety of each of these courses differs from university to university as well as from degree program to degree program.[33] The myriad of different course sequences that have been approved by implication via the accreditation of the degree programs to which they belong by the ABET process are too numerous to present in this Comment. Rather than attempting to catalog all the various options, the following Sections will describe the characteristics of many of the projects and then describe typical capstone senior design project types used by specific degree programs at the Milwaukee School of Engineering.[34]

1. Typical Characteristics of Capstone Senior Design Projects

There are a number of motivating factors that drive the format and content of a typical capstone senior design project in engineering. An engineering degree program desiring to provide work-ready graduates will endeavor, as much as is reasonably feasible in the academic environment, to simulate an actual engineering project.[35] And while the typical engineering project varies greatly between disciplines and industries, there are a number of characteristics that are generally common across these projects.

The characteristics of a typical capstone senior design project, while ultimately driven by industry, are also covered in many cases by elements of ABET's Criterion 3. The industry project model is very consistent with Criteria 3(c), 3(e), and 3(k), which require that graduates have the "ability to design a system, component, or process to meet desired needs within realistic constraints,"[36] the "ability to identify,

33. *See, e.g.,* MILWAUKEE SCHOOL OF ENGINEERING, STUDENT PROJECTS 2005-2006 1 (Sue Miller ed.) (2006) (copy available from the author) [hereinafter PROJECTS 2006].

34. The Milwaukee School of Engineering is a small private university located in Milwaukee, WI. It is predominantly an undergraduate teaching university. It provides accredited undergraduate degree programs in architectural, biomedical, computer, electrical, industrial, mechanical, and software engineering as well as business, construction management, engineering technology, general engineering, nursing, and technical communication. This university was selected due to the ready availability of project information on the Internet as well as the author's general familiarity with the degree programs offered at MSOE as a faculty member within the computer and software engineering degree programs. For more information regarding MSOE, see http://www.msoe.edu.

35. *See* PROJECTS 2006, *supra* note 33, at 1.

36. Criteria 2000, *supra* note 15, at 2.

formulate, and solve engineering problems,"[37] and the "ability to use the techniques, skills, and modern engineering tools necessary for engineering practice."[38] In addition, it is quite common for capstone senior design projects to require that students work in teams (Criterion 3(d))[39] and that students document and communicate the results of their design efforts (Criterion 3(g)).[40] As a result of these requirements and students' natural interest in the latest technologies, students often take on and, to some extent, solve realistic engineering problems facing industry. Consequently, they are using state-of-the-art techniques, processes, and mechanisms during the course of their project that make it quite possible they could find themselves subject to the hypothetical presented at the beginning of this Comment.

While the common characteristics of capstone senior design projects may often place the students in danger of infringing on patents, it is not these characteristics that will determine whether they are eligible for the experimental use exception.[41] Of greater importance in examining the applicability of the experimental use exception to capstone senior design projects is how projects originate and the roles the university and industry play in sponsoring, motivating, and funding the projects. To better understand these characteristics, the following two Sections will look at three different types of capstone design projects in three degree programs at an engineering university.

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37. *Id.*

38. *Id.*

39. *Id.* *See also* PROJECTS 2006, *supra* note 33, at 1. The additional requirement in Criterion 3(d) that teams be "multidisciplinary" is not always realized in capstone senior design projects. *See id*. However, it is not uncommon to have teams comprised of students from multiple degree programs. *See* PROJECTS 2006, *supra* note 33, at 15-20.

40. Criteria 2000, *supra* note 15, at 2. *See also* PROJECTS 2006, *supra* note 33, at 1. Interestingly enough, this need to communicate the details of a design effort may also intersect with the experimental use exception to the one-year public use limitation of 35 U.S.C. § 102(b). *See supra* note 6.

41. *See infra* Part II.

2. Typical Projects in the Computer and Software Engineering Degree Programs at MSOE[42]

Students in the computer and software engineering degree programs at the Milwaukee School of Engineering are given great latitude in choosing both their design team and their project area.[43] Each student team is responsible for selecting its own project topic, and the team is encouraged to consider both its own technical interests as well as soliciting the companies at which they work for ideas.[44] The result of this process is typically two kinds of project. The first type of project, and most common, is the student-sponsored project that students choose entirely from their own areas of interest. The second type of project is one sponsored by local industry based upon some type of, generally low-priority, need that a company has. To better understand the characteristics of these two types of projects, examples of both are described below.

Student-sponsored projects are the most common type of capstone senior design project in both computer and software engineering at MSOE. The students on the design team assume full responsibility for the requirements and outcomes of the project.[45] The student-sponsored projects in these degree programs cover a broad range of topics ranging from software-only to mixed hardware-software projects. Three exemplary projects are the Stored File Tagging Utility (Tag Project), S-Link Media Center Controller (S-Link Project), and Automated Foosball Table (Foosball Project). The Tag Project is a software-only operating system extension that allows users of the extension to place custom labels on files that can be used to categorize and search for the

42. For a detailed list of projects from academic year 2005-2006, see PROJECTS 2006, *supra* note 32, at 15-21. Additional projects for academic year 2004-2005 can be found in MILWAUKEE SCHOOL OF ENGINEERING, STUDENT PROJECTS 2004-2005 12-17 (Sue Miller ed.) (2005) (copy available from the author) [hereinafter PROJECTS 2005]. Descriptions and documentation for many of the projects are available on the Internet. MSOE CE/SE Senior Design, http://jade.msoe.edu/ (last visited Feb. 21, 2008).

43. *See* MSOE Computer/Software Engineering Senior Design—Organizational Meeting Presentation, http://people.msoe.edu/~rothede/twiki/bin/view.cgi/SeniorDesign/OrganizationalMeetingPresentation (last visited Feb. 21, 2008). The faculty and local industry often provide a list of suggested topics for projects they are willing to sponsor. MSOE Computer/Software Engineering Senior Design—Project Ideas, http://people.msoe.edu/~rothede/twiki/bin/view.cgi/SeniorDesign/ProjectIdeas (last visited Feb. 21, 2008).

44. PROJECTS 2006, *supra* note 33, at 1.

45. This is perhaps a bit disingenuous. The capstone senior design projects are overseen by a faculty member who exercises sufficient oversight of the project to provide substantive aid in selecting a project of appropriate scope as well as to ultimately grade the project.

files.[46] The Tag Project was developed as a software package that is freely available for download on the Internet.[47] The S-Link Project team developed a consumer electronics device designed to interface a personal computer to Sony MegaStorage CD players through the use of Sony's S-link bus to control the CD player and to interface to Internet audio databases.[48] The Foosball Project team developed an automated foosball table that could play one-on-one versus a person. The automated foosball table combined a ball sensing system with actuators to control the playing rods.[49]

In each of these student-sponsored projects, the student teams chose the ideas themselves by selecting an area of interest and identifying a needed improvement or product in that area. With the supervision of a faculty advisor, they limited the project to a suitable scope and then designed and developed a working prototype. In each of these projects, the students also funded the project from their own pockets.[50]

A less common type of capstone senior design project in the computer and software engineering degree programs at MSOE is the industry-sponsored project. For these projects a company identifies a short-term, low-priority need and has the student design team develop a solution.[51] These projects have an added advantage in that the company acts as a major stakeholder that helps define the scope of the project and makes the team accountable for delivering a viable solution. In addition, as an interested sponsor, the company will often take on most of the funding for the project as these projects are typically beyond the financial reach of the student teams. A typical industry-sponsored

46. PROJECTS 2006, *supra* note 33, at 19.

47. Stored Tagging File Utility (Tag), http://jade.msoe.edu/tag/ (last visited Feb. 21, 2008).

48. PROJECTS 2006, *supra* note 33, at 19; Team S-Link, http://jade.msoe.edu/slink/ (last visited Feb. 21, 2008).

49. PROJECTS 2005, *supra* note 42, at 13; Automated Foosball Table Wiki, http://jade.msoe.edu/foosball/ (last visited Feb. 21, 2008).

50. The students themselves do not always fund 100% of the needs of the project. Industry often supports the projects through sample parts, limited services, and occasionally a scholarship. *See infra* Part I.C.2.

51. PROJECTS 2006, *supra* note 32, at 1. At least one member of the design team is typically an intern at the company sponsoring the project. *See id.* The university may also sponsor a project internally, but for the issues relevant to this Comment, the distinction between a university-sponsored and a company-sponsored project is irrelevant. For an example of a university-sponsored project see the Man at Work Project. PROJECTS 2006, *supra* note 33, at 18; Man at Work Self-Guided Tour Home Page, http://jade.msoe.edu/museum/ (last visited Feb. 21, 2008).

project is Team Soda's HK Systems Inventory Project that provides an inventory-tracking system for an IT department.[52]

3. Typical Projects in the Mechanical Engineering Degree Program at MSOE[53]

The mechanical engineering degree program at MSOE typically has an additional type of capstone senior design project that does not fit well in the previously described student-sponsored and industry-sponsored project categories. Unlike the computer and software engineering degree program projects that focus on the development of a product or the solution of an engineering problem, the mechanical engineering projects are often geared toward a national or international competition. The goal of many mechanical engineering project teams is to develop an entry for the design competition they have chosen. Typical kinds of design contests are the Institute for Affordable Transportation's Basic Utility Vehicle Competition and the Society for Automotive Engineers (SAE)'s Aero Open Design Competition.[54] Good showing by student design teams at these competitions helps raise the profile of degree programs at the various universities that participate and of the companies that sponsor the teams. Consequently, the projects are often funded by the students, the society sponsoring the contest, industry sponsors, and the university.[55]

Capstone senior design projects provide an excellent forum for soon-to-be graduating engineering students to showcase their abilities as engineers. These projects often cover a wide range of technical areas and provide engineering solutions that meet many needs. There are many types of projects, but three of the main types are the student-sponsored, industry-sponsored, and design-competition projects. Each relies on a different source for the project idea, and they are often sponsored and funded using different approaches.

52. HK Systems Inventory Project, http://jade.msoe.edu/hkinventory/ (last visited Apr. 10, 2008).

53. For a detailed list of projects from academic year 2005-2006, see PROJECTS 2006, *supra* note 33, at 27-30. Additional projects for academic year 2004-2005 can be found in PROJECTS 2005, *supra* note 42, at 25-27.

54. PROJECTS 2006, *supra* note 33, at 27, 29. Additional competitions include the SAE's MiniBaja Competition and the American Society for Heating, Refrigerating, Air-Conditioning Engineers (ASHRAE)'s Student Building Design Competition. *Id.* at 28.

55. E-mail from Joe Musto, Program Director for Mechanical Engineering, Milwaukee School of Engineering, to Henry Welch, Professor of Electrical, Computer, and Software Engineering, Milwaukee School of Engineering. (Nov. 20, 2006, 17:20:29 CST) (on file with author).

C. Comparing Graduate Research to Undergraduate Capstone Senior Design Projects

At first glance, it would appear that graduate research and capstone senior design projects share many characteristics in common. Both activities serve a broad academic purpose to educate students, they both are overseen by faculty, and they are both administered by largely non-profit universities. However, this superficial characterization of the two activities fails to uncover vast differences in the structure and expenditures on these very different activities. This Section will focus on these differences.

1. Characteristics of Graduate Research

Graduate research is a huge, multibillion dollar per year industry. According to a National Science Foundation survey, in fiscal year 2004, colleges and universities spent almost $43 billion on basic research and applied research and development.[56] Of this amount, over $30 billion came from government sources, $2 billion from industry, and the remainder from other sources.[57] Basic research accounts for 75% of these expenditures.[58] This is clearly big business and the colleges and universities rely in large part upon these funding sources to support their larger goals.

Graduate research is typically directed by a faculty member. Traditionally, the goal of this research was for general academic pursuits and publishing credits for these faculty members, as well as the education of the graduate students, but in recent years this has become more business focused.[59] To aid faculty members in this research, the various grants often include provisions that allow faculty members to hire research assistants. In the sciences and engineering, these assistants are typically graduate students who are receiving funded tuition and regular paychecks in the form of assistantships.[60] These graduate students are, in effect, employees of the university. They labor on behalf of the university to not only perform the research, but also to

56. NATIONAL SCIENCE FOUNDATION, ACADEMIC RESEARCH AND DEVELOPMENT EXPENDITURES: FISCAL YEAR 2004 9 (Jul. 2006), *available at* http://www.nsf.gov/statistics/nsf06323/pdf/nsf06323.pdf.

57. *Id.*

58. *Id.* at 11.

59. Rowe, *supra* note 2, at 923.

60. *See* SANDRA JOHNSON BAYLOR, CARLA ELLIS & ANN REDELFS, GRADUATE SCHOOL INFORMATION GUIDE 9 (2000), *available at* http://www.cra.org/Activities/craw/projects/mentoring/mentorWrkshp/grad-guide.pdf.

enhance the prestige of the university[61] and to increase the university's patent portfolio.[62]

2. Characteristics of Undergraduate Capstone Senior Design Projects

While it is true that most undergraduate engineering students receive merit-based scholarships from the universities they attend, most continue to subsidize their own educations through loans and other sources.[63] This is clearly different from the graduate student model where the graduate student often works as a research assistant and receives tuition and income in exchange.[64]

When the capstone senior design projects are examined, the financial equation becomes even more inverted. Like all college courses, in order to get credit for the capstone courses, the student must pay tuition. In this model it is not the student that works for the university, but rather the university and, more importantly, the faculty advisor who work for the student.[65] In addition, in many of the capstone senior design projects, the general impetus for the direction of the project effort comes from the student and not the faculty member or the grant awarded to the university or the faculty member. Thus, in many cases, the creative control lies with the student and not the faculty member.

Project funding is also different in the capstone senior design project model. With a graduate research project, the university typically covers most, if not all, of the expense as one would expect in a traditional employer-employee model. As previously described, this is not necessarily the case for capstone senior design projects.[66] For an industry-sponsored project, most of the expenses are borne by the sponsor.[67] With the design-competition project the funding is mixed,

61. This is a central element of the holding in *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002). This is discussed *infra* Part II.

62. Rowe, *supra* note 2, at 924.

63. Many undergraduate engineering students work as interns to help pay their tuition and living expenses.

64. *See* BAYLOR, ELLIS & REDELFS, *supra* note 60 at 9.

65. By this characterization I am not implying that the student acts as boss to the faculty member, but rather that the flow of funds is from student to professor, rather than professor to student. In most transactions, the person paying money is buying a service over which they have some control. Clearly education does not quite fit this model as the student is purchasing a service for which she knows in advance that the provider, i.e., the faculty member, will exercise the greater level of control.

66. *See supra* Part I.B.

67. This is, of course, the university when the university is the sponsor.

and with student-sponsored projects the funding is largely borne by the student.

All capstone senior design projects typically receive some indirect funding from industrial sources. This can vary from the donation of services, to free parts and equipment, to small monetary grants. A commonly donated service is the limited manufacturing of prototypes for printed circuit boards.[68] Many semiconductor manufacturers often provide samples of chips for prototyping purposes.[69] Others will provide nominal sponsorship for projects in limited technical areas.[70] In each of these situations, the funding is very indirect, and the industrial sponsor provides neither creative nor decision-making control over the project.

There are vast differences between graduate research projects and undergraduate capstone senior design projects in engineering. With graduate projects the funding and directive control lies almost exclusively with the university through a professor. With undergraduate capstone senior design projects, the funding and directive control lies more definitively with the students or, in the case of industrial-sponsored projects, outside the university. This will be significant when viewed in light of the experimental use exception to patent infringement as discussed in the following Sections.

II. Patent Infringement and the Experimental Use Exception

Section 271(a) of the Patent Act indicates that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . during the term of the patent therefore, infringes the patent."[71] And, while the Supreme Court's holding in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.* strongly suggests that the intent of the infringer is irrelevant to patent infringement,[72] the

68. Sunstone Circuits offers such prototypes to non-profit organizations and universities through their sponsorship program. Sunstone Circuits, http://www.sunstone.com/id/39/Sponsorship+Overview.aspx (last visited Apr. 9, 2008).

69. National Semiconductor is an example. *See* http://www.national.com/pf/master.html (last visited Apr. 9, 2008) (indicating that samples of some parts are available as an alternative to making a purchase).

70. Plexus Technology Group sponsors a limited number of projects each year in the computer and software engineering degree programs at MSOE for projects involving embedded systems. *See* PROJECTS 2005, *supra* note 42, at 14. Other than selecting teams based upon a proposal, Plexus has no active involvement in the content or direction of the sponsored projects.

71. 35 U.S.C. § 271(a) (2006).

72. 520 U.S. 17, 36 (1997); *see also* Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University*

Federal Circuit "continues to recognize the . . . experimental use [exception] . . . in a very limited form."[73] The following Sections of this Comment will explore the origins and history of the experimental use exception including its modern interpretation by the Federal Circuit as well as recent changes in federal law as it pertains to experimental use. Based upon this analysis, rules regarding experimental use that can be applied to capstone senior design projects will be determined.

A. Origins and Development of the Experimental Use Exception

The experimental use exception has been part of the legal landscape of patent law for nearly two centuries. It has long been recognized as a common law defense to patent infringement when the infringing acts "are conducted solely for the purpose of scientific inquiry."[74] The origins of the exception can be traced to the 1813 opinion in *Whittemore v. Cutter*, in which Judge Story stated "that it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."[75] Story's use of the term "philosophical" is somewhat confusing until one realizes that he was referring to "natural philosophy" which has been largely replaced by the modern term "scientific."[76] Thus, Story was describing a defense to infringement when the alleged infringer was motivated by scientific curiosity and not by profit; an interpretation he would subsequently reiterate in *Sawin v. Guild*.[77]

The experimental use exception appears to have become firmly entrenched as a common law defense with the decision in *Poppenhusen v. Falke* in 1861.[78] In *Poppenhusen*, the court held that infringing activities that were "for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, [were] not an infringement of the rights of the patentee."[79] This holding clearly established that the

and Nonprofit Research and Development, 56 BAYLOR L. REV. 917, 935 n.85 (2004).

73. Madey v. Duke Univ., 307 F.3d 1351, 1360 (Fed. Cir. 2002).

74. Cai, *supra* note 2, at 176.

75. 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600).

76. Mueller, *supra* note 72, at 929 n.44.

77. 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391).

78. 19 F. Cas. 1048 (C.C.S.D.N.Y. 1861) (No. 11,279).

79. *Id.* at 1049.

profit motive of the infringer was the determinative factor in evaluating whether an infringement was an allowable experimental use.[80]

Prior to the Federal Circuit's ruling in *Madey v. Duke University*,[81] the controlling case as to how the experimental use exception applied to universities and their research was the 1935 decision in *Ruth v. Stearns-Rogers Manufacturing Co.*[82] In *Stearns-Rogers*, the defendant was found liable for contributory infringement for selling parts to a patented floatation device.[83] However, the court expressly exempted the sales of those parts made to the Colorado School of Mines that were used for conducting research, stating that "[t]he making or using of a patented invention merely for experimental purposes, without any intent to derive profits or practical advantage therefrom, is not infringement."[84] Prior to 2002, academic institutions have interpreted this decision as giving them broad protection from patent infringement during the course of research.[85]

B. Narrow Interpretation of the Experimental Use Exception and the Federal Circuit

Until recently, the profit motive of the alleged infringer appears to have been the primary test used by courts when applying the experimental use exception.[86] This test, though, has shifted in recent years to an analysis of whether the infringing activity is related to the legitimate business interests of the infringer.[87] This Section will examine this shift in reasoning by the courts and address its implications to universities and their research.

One of the first clear indications of the shift to the legitimate business interests test is found in the Court of Claims holding in *Pitcairn v. United States*.[88] In *Pitcairn*, the United States government argued that its experimental testing of infringing helicopters for evaluation and demonstration purposes should be exempt from infringement under the experimental use exception.[89] The court rejected this argument, stating

80. Rowe, *supra* note 2, at 927-28.
81. *See infra* Part II.B.
82. 13 F. Supp. 697 (D. Colo. 1935), *rev'd on other grounds*, 87 F.2d 35 (10th Cir. 1936).
83. *Id.* at 713.
84. *Id.*
85. Rowe, *supra* note 2, at 928.
86. *Id.* at 927-28.
87. *Id.* at 928.
88. 547 F.2d 1106 (Ct. Cl. 1977).
89. *Id.* at 1125.

that tests, demonstrations, and evaluations were within the intended uses of the helicopters.[90] The court further held that because the intended use was "in keeping with the legitimate business of the using agency," the experimental use exception did not apply.[91] This shift in focus was to have significant implications to the reasoning of the Federal Circuit.

The Federal Circuit first addressed the experimental use exception in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*[92] In an effort to jump-start the development of the generic equivalent for an established drug, Bolar chose not to wait for the expiration of Roche's patent before beginning its efforts to obtain federal approval of its generic equivalent.[93] Relying heavily on the precedent of *Pitcairn*, the Federal Circuit reinforced the narrow interpretation of the experimental use exception.[94] In reaching this conclusion, the Federal Circuit specifically held that it could not "construe the experimental use rule so broadly . . . in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes."[95] This ruling firmly installed legitimate business interests as the operative test for the experimental use exception.

The Federal Circuit reiterated its reliance on the legitimate business interests test, as outlined in *Roche*, in its 2000 ruling in *Embrex, Inc. v. Service Engineering Corp.*[96] In *Embrex*, the Federal Circuit held that just because the defendant was not able to sell its infringing machines did not mean that it was immune from infringement when it upheld the district court's judgment as a matter of law on the issue of infringement.[97] *Embrex*, however, is probably better known for its concurring opinion by Judge Radler. In his concurrence, Judge Radler felt that the holding in *Warner-Jenkinson* all but eliminated the experimental use exception, stating that the "slightest commercial implication" would render the exception inapplicable.[98] At least one commentator believes that Judge Radler has overstated the implications

90. *Id.*
91. *Id.* at 1125-26.
92. 733 F.2d 858 (Fed. Cir. 1984).
93. *Id.* at 860. It should be noted that this type of activity has since been protected by the Hatch-Waxman Act. *See infra* Part II.C.
94. 733 F.2d at 863.
95. *Id.*
96. 216 F.3d 1343, 1349 (Fed. Cir. 2000).
97. *Id.*
98. *Id.* at 1353 (Radler, J., concurring).

of *Warner-Jenkinson* and that there is still an intent-based exception to patent infringement for experimental use.[99]

While the *Stearns-Rogers* holding has generally been interpreted to give broad immunity for patent infringement to university research,[100] this case does not reflect the subsequent legal landscape regarding intellectual property and universities. In 1980, Congress passed the Bayh-Dole Act,[101] which allowed non-profit organizations (e.g., universities) and small businesses to retain title to inventions funded by government research monies.[102] As a result of this and other market forces, university research has become less about scientific inquiry and more about business.[103] In fact, university revenues from patent licenses and royalties are now an annual multibillion dollar activity.[104] The Federal Circuit has recently taken notice of this.

In 2002, the Federal Circuit addressed the issue of university research and the experimental use exception in light of these modern developments with the case *Madey v. Duke University*.[105] In 1989, Dr. John Madey moved his laser research lab from Stanford University to Duke University.[106] Madey also held the rights to two exclusive patents practiced by some of the equipment in that lab.[107] After a disagreement, Madey resigned from Duke and subsequently sued Duke for patent infringement after Duke continued to operate some of the lab equipment.[108] Relying heavily on *Pitcairn* and *Embrex*, the Federal Circuit reiterated the legitimate business interests test.[109] The Federal Circuit further stated that the district court, in allowing the exception, placed too much weight on the non-profit educational status of Duke.[110] The court further held that many of Duke's legitimate business interests were furthered by the infringing use "including educating and enlightening students and faculty participating in these projects. . . .

99. Mueller, *supra* note 72, at 935 n.85. The Federal Circuit also continues to recognize the exception. Madey v. Duke Univ., 307 F.3d 1351, 1360 (2002).

100. *See supra* Part II.A.

101. H.R. 6933, 96th Cong. (1980); 94 Stat. 3015 (codified as amended at 35 U.S.C. §§ 200-212 (2006)).

102. 35 U.S.C. § 202(a).

103. Rowe, *supra* note 2, at 923.

104. *Id.* at 924.

105. 307 F.3d 1351 (Fed. Cir. 2002).

106. *Id.* at 1352.

107. *Madey*, 307 F.3d at 1351.

108. *Id.* at 1353.

109. *Id.* at 1362.

110. *Id.*

[And they] also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty."[111] Thus, the Federal Circuit found that the infringing activities "appear to be in accordance with any reasonable interpretation of Duke's legitimate business objectives" and remanded the case for consideration on those grounds.[112] This holding has been soundly criticized.[113] Despite their non-profit status, universities now find themselves under the same narrow interpretation of the experimental use exception as previously applied only to profit-seeking businesses.

Until and unless *Madey* is overruled, the operative test for the experimental use exception continues to be whether the infringing activities are within the legitimate business interests of the infringer and not whether the infringer intends to make a profit or operates a non-profit organization.[114] This provides a very narrow interpretation of the exception where there are no business interest implications for the infringing activity.

C. New Life: The Food and Drug Administration Safe Harbor

The experimental use exception, however, does not continue to be narrowly interpreted in all instances of patent infringement.[115] Recent changes in federal law have breathed new life into the exception in the area of drug research, which has been subsequently reinforced by the Supreme Court.[116] This Section will discuss these changes in the experimental use exception and how they affect the legitimate business interests test.

The Federal Circuit's decision in *Roche* resulted in significant controversy. If generic drug manufacturers could not start testing their new drugs until after the patent protecting the original drug expired, this would effectively extend the lifetime of the original patent because the drug approval process often takes years.[117] Congress addressed this issue by passing the Drug Price Competition and Patent Term

111. *Id.*

112. *Id.* at 1362-63.

113. *See, e.g.*, Mueller, *supra* note 72, at 940-45.

114. *See Madey,* 307 F.3d at 1362-63.

115. *See, e.g.,* Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act, S. 1538, 98th Cong. § 101 (1984) (codified in part as 35 U.S.C. § 271(e)(1) (2006)) [hereinafter Hatch-Waxman Act].

116. Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005).

117. Rowe, *supra* note 2, at 932.

Restoration (Hatch-Waxman) Act of 1984.[118] This Act is, in effect, "a codified version of the experimental use exception for the pharmaceutical industry."[119] The Supreme Court has since interpreted this Act quite broadly and applied it to medical devices, food additives, and other products requiring lengthy FDA approval.[120]

The Supreme Court's reasoning is clearly exemplified in its vacation of the Federal Circuit's ruling in *Integra Lifesciences I, Ltd. v. Merck KGaA* [hereinafter *Integra I*] with its ruling in *Merck KGaA v. Integra Lifesciences I, Ltd.* [hereinafter *Integra II*].[121] In *Integra I*, the Federal Circuit continued its very narrow interpretation of the experimental use exception by limiting infringing activities allowed under 35 U.S.C. § 271(e)(1) to only "those [activities] necessary to acquire information for FDA approval."[122] The Federal Circuit effectively held that experiments that were not ultimately included in the FDA submission were infringing activities not protected by the safe harbor.[123]

In *Integra II*, the Supreme Court soundly rejected this argument when it vacated the holding of *Integra I*.[124] The Supreme Court interpreted the "reasonably related" language of 35 U.S.C. § 271(e)(1) quite broadly when it concluded that the exception applied to any activities "'reasonably related' to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs."[125] This provides a broad interpretation to the experimental use exception in the context of drug development and covers experiments that ultimately turn out to be unsuccessful.[126]

This broad interpretation of the experimental use exception has significant implications for university research and activities that are undertaken as part of a governmental approval process in medically related fields. It immunizes large aspects of research endeavors as long as they can be found to be "reasonably related" to the approval process.

In its nearly two-century lifetime, the experimental use exception has evolved from its common law beginnings. Originally conceived as a

118. Hatch-Waxman Act, S. 1538, 98th Cong. § 101 (1984) (codified in part as 35 U.S.C. § 271(e)(1) (2006)).

119. Rowe, *supra* note 2, at 932.

120. *Id.* at 933.

121. 545 U.S. 193 (2005).

122. 331 F.3d 860, 867 (Fed. Cir. 2003) (2-1 decision), *vacated*, 545 U.S. 193 (2005).

123. Rowe, *supra* note 2, at 933.

124. *Integra II*, 545 U.S. at 208.

125. *Id.* at 206 (emphasis in original).

126. Rowe, *supra* note 2, at 933-34.

defense applicable when the infringing activities were merely philosophical in nature,[127] it eventually evolved into a test of the profit motives of the infringer.[128] In more recent years the experimental use exception has been even more narrowly interpreted as a measure of whether the infringing activity is part of the legitimate business interests of the infringer and not the for-profit or non-profit status of the infringer.[129] A broad interpretation has also been statutorily created in the biotechnical fields.[130]

III. THE EXPERIMENTAL USE EXCEPTION AND CAPSTONE SENIOR DESIGN PROJECTS

It has never been tested in the courts whether undergraduate educational activities, such as capstone senior design projects, are eligible for the experimental use exception. A superficial examination of the holding in *Madey v. Duke University* might suggest that the experimental use exception is no longer available to universities, but *Madey* only applies in the case of academic research.[131] There are significant differences in both the funding models and motivating factors between graduate research and capstone senior design projects.[132] For some capstone senior design projects, these differences are sufficient to distinguish them from the holding in *Madey* as it was applied to graduate research.

The following Sections will examine the three types of capstone senior design projects: industry-sponsored, design-competition, and student-sponsored. Each type will be examined in light of the legitimate business interests test that is currently used in the Federal Circuit for applying the experimental use exception to patent infringement.[133] These Sections will specifically not be addressing any special applicability of the Hatch-Waxman Act and its subsequent jurisprudence[134] to capstone senior design projects in biomedical engineering as its applicability would depend upon the specific project. This examination will hopefully shed some light on the advice an attorney could give Joe from the opening hypothetical.

127. Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600).
128. Rowe, *supra* note 2, at 927-28.
129. *See supra* Part II.B.
130. *See supra* Part II.C.
131. Cai, *supra* note 2, at 175.
132. *See supra* Part I.C.
133. *See supra* Part II.B.
134. *See supra* Part II.C.

A. Industry-Sponsored Projects

In an industry-sponsored capstone senior design project, the impetus and general direction of the project are typically provided by a company. In exchange for addressing a short-term, low-priority need for the company, the students gain the valuable experience of working for a real project stakeholder as well as receiving a significant source of funding for their prototyping efforts from the company.[135] When this relationship and the motivating factors for the project are viewed in light of the legitimate business interests test, it is quite clear that the experimental use exception would not be available as a defense to patent infringement. The students working on the project are clearly seeking a solution that addresses, at least on some level, a legitimate business interest of the company sponsoring the project. This would disqualify the students from claiming the experimental use exception and may even make the sponsoring company liable as an inducing infringer.[136]

It is possible, under some rare scenario, that the company may argue that it was simply being a good corporate citizen in sponsoring the project and that it had no real stake or specific interest in the outcome of the project.[137] However, by behaving as an active stakeholder and funding source for the project, the company will be unlikely to show that the project was not addressing one of its legitimate business interests.

Consequently, it is unlikely that the experimental use exception would be applicable to an industry-sponsored capstone senior design project.

B. Design-Competition Projects

In a design-competition capstone senior design project, the impetus and general direction of the project are provided by an outside professional or technical society.[138] Each year these societies sponsor

135. *See supra* Part I.B.2.

136. As this depends on whether the company intended to induce infringement of the patent, it would require further analysis based upon the specific knowledge of the company with regard to the patent in question. *See* 35 U.S.C. § 271(b) (2006).

137. This is similar to the sponsorship arrangement practiced by companies like Plexus Technology Group. *See supra* note 70. In this case, however, Plexus takes no active role in the project other than nominal funding, and the nexus between Plexus and the direction of the project is insufficient to defeat any implication that the project is related in a substantive way to a legitimate business interest of Plexus. *Id.*

138. *See supra* Part I.B.3.

national and international competitions for which the capstone senior design teams design and develop an entry. These projects are often funded through a combination of university funds, industrial sponsorship, and student self-funding.[139] A good showing at these competitions by the student teams provides bragging rights for their universities, which may also lead to better student recruiting and increased industrial sponsorship for future entries.[140]

Taken as a whole these factors seem to address all of the factors the Federal Circuit identified as satisfying a legitimate business interest of the university. Specifically, the projects "educat[e] and enlighten[] students and faculty participating in these projects. . . . [And they] also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty."[141] If this is judged to be the case, then the experimental use exception is clearly not applicable to a design-competition project. However, the similarity is not so complete that this might not make for a colorable case. First, there is a much lower likelihood that the faculty involved with the project will be educated in a comparable way as a faculty member involved in graduate research. Further, and more importantly, while the projects do serve "to increase the status of the institution and lure . . . students,"[142] it is rather unlikely that these projects result in "lucrative research grants" and in improved hiring of faculty.[143]

Because the Federal Circuit did not separate these various factors nor state how it weighed them in the *Madey* case, it is unclear which factor might take more weight than others. If the Federal Circuit is disposed to put significant weight on the lack of lucrative grants stemming from the successful projects and shift back to the earlier profit motive test for the experimental use exception, then it is quite possible that the exception may be available for a design-competition project.[144]

On balance, though, this is pure speculation, and given the general trend of the Federal Circuit to very narrowly interpret the experiment use exception,[145] it is still unlikely that it would be available as a defense to patent infringement for design-competition projects.

139. *See supra* note 54.
140. *See supra* Part I.B.3.
141. Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002).
142. *Id.*
143. *See id.*
144. *See supra* Part II.A.
145. *See supra* Part II.B.

C. Student-Sponsored Projects

In a student-sponsored capstone senior design project, the impetus and general direction of the project are provided almost exclusively by the students working on the project.[146] And while the project is being nominally supervised by a faculty member, this is done more for educational purposes with regard to teaching the students engineering process and the ultimate need to grade the project than for the specific technology involved. The differences between this type of capstone senior design project and graduate research are so significant that the factors outlined in the *Madey* decision are largely inapplicable here.[147]

The economic model for the student-sponsored capstone senior design project is completely inverted from that of graduate research. With the capstone senior design project, all the funds flow from the student to the university or the project rather than from the university to the students and research.[148] The nexus between the legitimate business interests of the university and the project is tenuous at best.[149] The university is not directing the project other than as necessary to assess the performance of the students. It is simply providing a venue for the project, but in the final analysis it is student tuition money that is funding the university's share of the costs, and the legitimate business interests that should be examined are those of the students.

The students clearly have a legitimate interest in the success of their project. A passing grade is necessary to obtain an engineering degree, and this, in turn, is necessary, in most cases, to landing an engineering job and the start on what will hopefully be a successful career. Yes, in some small part the students are motivated by a profit motive—the waiting lure of an engineer's salary—but the relationship is indirect at best. The capstone senior design project is simply a means to that end, and the project itself is not being directly undertaken for a profit motive.[150] There is no lucrative follow-up research grant at the conclusion of the project.

146. *See supra* Part I.B.2.

147. *See Madey*, 307 F.3d at 1362.

148. *See supra* Part I.C.

149. Yes, the project does relate to the university's legitimate business interest in educating the students, but that is only one factor in the *Madey* holding. *See Madey*, 307 F.3d at 1362.

150. This is perhaps not true in all situations. Some students may be pursuing their project as the potential source for a start-up or other business venture. This would clearly balance the factors more in concert with the legitimate business interests test, and thus the project would more closely resemble an industry-sponsored project with the students acting

Other than an individual working in a basement workshop, it is hard to imagine a scenario more in concert with the ideal espoused by Story's "who constructed . . . a machine merely for philosophical experiments" test proposed nearly 200 years ago in *Whittemore v. Cutter*.[151] The students have undertaken the project simply to learn and educate themselves, and while the passing grade and its intended consequences will result, this hardly seems any less altruistic than the individual in the basement workshop who may eventually capitalize on his newly gained knowledge to enhance his career.

The experimental use exception is still a viable defense to patent infringement for a student-sponsored capstone senior design project. The students involved in the project are pursuing the project for precisely the same kind of philosophical goals as Story identified when he created the experimental use exception.[152]

CONCLUSION

The experimental use exception has enjoyed a long history as a common law defense to patent infringement. First proposed nearly two centuries ago by Judge Story, it provides a defense to an infringer who has infringed without commercial motives.[153] Despite a very narrow interpretation, in recent years, of the experimental use exception by the Federal Circuit using the legitimate business interests test, the exception is still viable as a defense.[154] Following the *Madey v. Duke University* decision it was felt that the experimental use exception was no longer available as a defense to universities when defending their research activities.[155] And while this is likely true, this is not the case for undergraduate capstone senior design projects.

As this Comment has demonstrated, there is limited viability for the experimental use exception for capstone senior design projects.[156] The viability depends on whether the project is industry-sponsored, design competition, or student-sponsored. In the case of industry-sponsored projects the exception is almost certainly unavailable as a defense because the industrial involvement would directly run afoul of the

as their own industry sponsor. *See supra* Part III.A. For the sake of the analysis, the author assumes that this is not the case.

151. 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600).

152. *See id.*

153. *See supra* Part II.A.

154. *See supra* Part II.B.

155. *See supra* Part II.B.

156. *See supra* Part III.

legitimate business interests test.[157] For design-competition projects the conclusion is somewhat mixed as to whether the exception is available as a defense, but on balance it would likely not be available.[158] Student-sponsored projects have the greatest likelihood of having the exception available as a defense.[159]

So in answer to the hypothetical question posed by Joe to his aunt in the introduction, it depends. What kind of capstone senior design project are you involved in?

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157. *See supra* Part III.A.
158. *See supra* Part III.B.
159. *See supra* Part III.C.

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