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Intellectual Property in Medical Imaging and Informatics: The Independent Inventor's Perspective

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While innovation and new product development is traditionally thought of as the exclusive domain of industry and academia, a large number of innovations in medicine and information technology have come from independent inventors, which account for almost 30% of new patents issued in the U.S. today. A large number of economic, political, and legal challenges exist within the current marketplace that serves as relative impediments to independent invention. This article explores the existing challenges facing the independent inventor and offers a number of recommendations and resources to facilitate independent inventors in their quest for innovation and entrepreneurship. The concept of "outsourcing innovation" is discussed as an alternative to the existing model of industry sponsored research and development (R&D), with the goal of combining the unique attributes and strengths of independent inventors and industry sponsors.

KEY WORDS: Intellectual property, invention, medical informatics

> Learning and innovation go hand in hand. The arrogance of success is to think that what you did yesterday will be sufficient tomorrow. William Pollard

INTRODUCTION

Intellectual property (IP) is defined as property that can be protected under federal law, including copyrightable works, ideas, discoveries, and inventions.[1] Most research and publications on IP focus on technological development within companies and industries[2,3] and on academic and government laboratories.[4,5] This focus is both the result of and reinforcement for the misconception that modern technological innovation is the purview of industry and academia.

In reality, many of the most influential and innovative medical and information technology (IT) inventions have been created by independent inventors, including: Wilson Greatbatch, who patented the implantable cardiac pacemaker; Raymond Damadian first described the concept of nuclear magnetic resonance and patented the first commercial unit; Raymond Kurzweil patented and marketed the first omnifont optical character recognition system and numerous speech recognition innovations; and Linus Torvalds wrote the program that became the Linux kernel.

Despite the many remarkable achievements of independent innovators, numerous technical, economic, political, legal, and educational challenges confront independent invention. This article is written to serve as an educational resource and guide to the fledgling independent inventor in imaging informatics, with the hope of encouraging entrepreneurship, innovation, and creativity within the existing constraints of a field dominated by industry-initiated research and development (R&D).

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Data on Independent Invention

The U.S. Patent and Trademark Office (USPTO) defines an independent inventor as one whose patent (at the time of issuance) is unassigned or assigned to an individual. The percentage of patents issued to independent inventors declined from 36.4% in 1987 to 26.8% in 1999.[6] International patent data (1999) show great variability in the overall percentages of patents issued to independent inventors, with less industrialized countries having a higher percentage of independent invention (75% in Hungary and 66% in Brazil, for example), compared with more industrialized countries (26% in both the United Kingdom and United States[6]).

Although the relative percentage of patents issued to independent inventors has gradually decreased over time, the total number of patents awarded to independent inventors increased by approximately 30% from 1990 to 2000.[7] These figures suggest that independent invention is alive and well in the United States and retains a vital role in innovation throughout industry and the marketplace.

A recent survey published by Weick and Eakin[8] explored the role and economic viability of independent inventors in the United States. Survey data revealed 83% of independent inventor respondents were "part-time" inventors, and 17% were "full time" inventors. Eighty-four percent of inventor respondents reported developing working prototypes of their inventions within the past 5 years. The top invention categories were dominated by hardware/tools, household, and industrial/commercial products, and the most frequently cited scientific/technology inventions were categorized as electronics (13%) and medical/therapeutic (12%).

Thirty-nine percent of respondent inventors reported generating sales from their inventions (mean sales, $3.5 million; median sales, $50,000), and 22% reported profitability (mean profit, $1.96 million; median profit, $75,000). The three principal means of IP commercialization included development of start-up companies (55% of respondents), licensing IP to another company (44% of respondents), and outright sales of IP (16% of respondents). Inventors who elected to license their inventions to others were more likely to achieve a higher level of overall sales than those attempting to commercialize the IP themselves or who sold the IP to a third party. This corroborates previously reported findings by Khan and Sokoloff,[9] who reported independent inventors' commercial success to be greatest through licensing agreements.

Existing Limitations of Industry-Sponsored R&D

The prevalent paradigm of industry-sponsored R&D suffers from several limitations, some of which are outlined in Table 1. The various strengths that provide industry with a distinct (and arguably unfair) advantage over the independent inventor paradoxically provide a disincentive toward innovation. This can be explained in part by the life cycle of innovation embraced by many companies, particularly larger and more financially successful concerns.

In the first stage (infancy) of this life cycle, innovation plays the dominant role in creating new IP, a process that provides the impetus and backbone for the original creation of many companies. The fledgling company is founded by a few energetic, industrious, and optimistic inventors who, through a combination of idealism, capitalism, and naivety, decide to embark on the development of a start-up company despite long odds against success. In the second stage (childhood), the company grows through successful commercialization of their innovation and IP. As the company grows and achieves economic success, the culture begins to shift from optimism and innovation to pragmatism and risk aversity. The political and economic realities of the marketplace begin to surface, and the founders of the company often turn over operational control to financial and management "professionals." If the company continues on a path of relative independence (avoiding merger or acquisition) and continues to achieve greater success in the marketplace, it may then enter stage 3 (adulthood), in which it is often transformed from "innovator" to "predator." In

Table 1. Existing Limitations of Industry-Sponsored R&D

Limitation
A follow-the-pack (lemming) mentality
Small, incremental approaches to new IP
Internal corporate politics and constraints
Short-term outlook targeted at immediate gratification
Product development done in "back rooms"
Limited input from "frontline" users
Reactive, not proactive, approach to market needs

entering this stage, the company often grows by acquiring smaller (and more innovative) companies, thereby expanding its product line and IP pipeline.

The large "predatory" company now responds to market economics, with product development largely dictated by the perceived needs of the customer base. Invention is typically performed within the company ("in house") by individuals who are often constrained by company politics and the economics of immediate gratification. The typical corporate mindset is to "play not to lose" rather than "play to win". As a result, innovation is largely stifled and relegated to product line developments and "incremental" improvement. It is ironic that the very company that was initially created by innovation and creativity becomes transformed into one that strives to stifle (and often crush) the creativity of the independent (and innovative) inventor.

In this life cycle, inventors themselves are no longer frontline users but, instead, are technicians and engineers. In the medical domain, these engineers are, for the most part, technology savvy, but clinically uninformed. As a result, refinements and new developments are based, at best, on minimal knowledge of how the product will truly function in the clinical environment. When clinical input is included, it is typically done by "experts" on a medical advisory board who have little practical experience outside of academia. As a result, even with a gloss of medical input, many products are developed within a rigid corporate culture by nonclinicians who are highly risk averse and focused on short-term horizons.

The independent inventor, on the other hand, is not bound by the same corporate constraints and, instead, can bring a fresh and practical perspective to product innovation. This strategy of "outsourcing innovation" is uncommon within industry today but offers the potential to create new independent inventor–industry synergies. The creation of an open market approach to innovation provides a cost-effective and practical means for companies to remove their self-induced IP constraints and seek out inventors from external sources to enhance innovation within new and existing product lines.[10,11]

Defining the Invention Process

Table 2 outlines a ten-step iterative process for invention and product development. The first step is to define an existing problem or deficiency in everyday practice. One example comes from my own work in private practice radiology, where one of my biggest concerns is the paucity of objective quality assurance (QA) metrics and standards within medical imaging and the lack of supporting technology. With the sole exception of mammography,[12] no medical imaging modality has rigorous and mandatory QA standards, despite a broad agreement on the significance of the role of medical imaging QA in clinical and economic outcomes.[13] Simply stated, QA in its present form is largely idiosyncratic and often nonexistent.

Table 2. Stepwise Approach to Invention Process

Approach
Define an existing problem or question
Review the current technical solution
Identify existing limitations and inefficiencies
Collect data using existing technology
Devise an alternative solution (invention)
Develop a prototype
Collect data using the prototype
Refine the prototype based on data and end-user feedback
Repeat data collection (and refinement as necessary)
Commercialize invention

In attempting to objectively quantify existing QA practice, we performed several studies evaluating QA-related workflow, technology, and variability and the related effects on image quality.[14–17] The results have indicated that the current practice of medical imaging QA is fraught with error and inconsistencies, resulting in inefficient workflow, reduced technologist productivity, poor image quality, and suboptimal radiation dose to patients. The data call for a complete revamping in the clinical and technical ways in which QA activities are implemented.

Defining the solution becomes fairly straightforward when confronted with the paucity of data, lack of standards, wide inter- and intradepartmental variability in performance, and lack of supporting technology for QA assessment. The ideal solution to improve current inefficiencies would be an automated system to record, measure, track, analyze, and provide QA feedback to practitioners.

After identifying and defining this deficiency, I proposed and described one such solution and submitted it for review by the USPTO. Although the idea may appear sound, it is only as good as the working prototype. As an independent inventor, I did not have the technical or economic resources required to create a working prototype

Table 3. Practical Advice for Inventors

Advice
Expect success to take 5–10 years
Do not quit your day job
Engage professional legal services for
Prior art search
Patent preparation
Nondisclosure agreements
Commercialization
Document everything!
Do not market until you receive notice of allowance
Be a little paranoid; expect dishonesty
File a provisional patent ASAP
Consider licensing as a means to commercialize
Leverage existing practical knowledge and experience
Think out of the box!
Leverage existing resources

and, therefore, elected to seek industry partnership through a licensing agreement. The project is far from complete, but the sequence of events outline in Table 2 are those that I have come to recognize as requisite for creation and implementation of an invention, with the ultimate goal of creating independent inventor–industry collaboration and a final product based on a data-driven engineering process.[18]

Practical Advice for Inventors

Table 3 is a list of practical suggestions for the independent inventor. First and foremost is the reality that inventorship is equivalent to running a marathon, not a sprint. Even under the best of circumstances, the patent review process takes 2–3 years and often longer, depending on the USPTO backlog, the initial review of the patent examiner, and what "prior art" (previously filed similar or analogous patents) is identified in the search process. Once the review process has been completed, the inventor must begin the arduous task of marketing the invention and/or developing a prototype. Because of the intensive resource requirements for prototype development, many inventors elect to pursue a licensing agreement with an established company that has the technical, financial, personnel, and legal resources to commercialize the patent and defend against potential future litigation. Securing a patent does not preclude the appearance of a predatory company that commits infringement. The best deterrent is an ally with deep pockets and the combined economic and legal clout to punish any violators.

The patent application process in the United States typically costs in the range of $20,000–$30,000. The result is that many independent inventors are forced either to abandon their IP or seek external funding sources. Although third parties exist in the form of independent investor and venture capitalist consortia, the inventor sometimes forfeits substantial economic and legal rights in entering such agreements. Having sound legal advice with expertise in patents and licensing is critical in ensuring that the best interests of the inventor (and the long-term security of his or her IP) are protected. New legislation is currently pending in Congress (HR 2795) that calls for major patent reforms. Enactment of this legislation could have negative effects on the independent inventor by:

1. Changing the definition of inventor from "first to invent" to "first to file";
2. Limiting a patent holder's rights to obtain a permanent injunction against an offending third party;
3. Creating a post-patent grant opposition proceeding; and
4. Limiting damages for infringement lawsuits

In the end, larger corporations and academic institutions have far more extensive resources and expertise to create, manage, and defend patents. These disproportionate resources should not preclude the independent inventor from seeking patents but should provide significant incentives to pursue symbiotic partnerships with industry that can ultimately benefit both parties.

Although "do it yourself" programs are widely advertised as ways for independent inventors to draft their own patent applications, investors should be wary of the long-term ramifications of even minor errors in the patent process. Claim wording on patents is complex and most properly the province of specialized attorneys with extensive training and experience. The prior art search is another integral component of patent preparation that should be

Table 4. Existing Resources for the Independent Inventor

Resource	Url
U.S. Patent & Trademark Office	http://www.uspto.gov
United Inventors Association	http://www.uiausa.org
Inventor Ed Inc.	http://www.inventored.org
Invent Net	http://www.inventnet.com
Index to U.S. Patent Classification	http://www.ibiblia.org/patents/index.html
Lemelson Foundation	http://www.lemelson.org

performed by skilled and experienced personnel. It is also essential to have the representation of a dedicated attorney in negotiating potential partnerships and collaborations, particularly in drafting a well-constructed nondisclosure agreement (NDA), which serves to protect the IP of both parties.

Trust and loyalty are admirable qualities, but the independent inventor must be cautious when discussing and exchanging IP. This takes on even greater importance with the impending Congressional legislation that provides IP ownership to the "first to file", as opposed to the traditional "first to invent." An independent inventor should, therefore, forego discussions related to "new" IP until after a provisional patent has been submitted and then only with a mutually signed NDA. To quote Andy Grove, former CEO of Intel, "only the paranoid survive."

In the event that patent litigation occurs and two parties are vying for patent ownership, or one party is challenging the validity of a recently issued patent, the courts will look for dated documentation to determine which party was "first to invent." As a result, it is imperative that the independent inventor document everything related to the invention from concept creation, to embellishment, to all forms of communication with third parties.

Most important, the intrinsic value of one's own creativity, practical knowledge, and experience should not be underestimated. Having the luxury of being independent and unconstrained by corporate shackles can be a distinct advantage to the independent inventor. In-house patent applications must pass through serial scrutiny that often serves to squash innovation and unorthodox thinking. The independent inventor does not have these limitations and is, instead, free to explore any and all creative concepts, regardless of the existing product pipeline. Although market viability and compatibility with a company's strategic planning remain critical points of analysis for potential inventor–industry partnerships, the independent inventor should continuously strive to "push the envelope" and leverage his or her own unique insights and experience.

The new independent inventor should take advantage of existing resources that can provide valuable insights, contact information, and educational programs. Several of these Internet-based resources are listed in Table 4 and serve merely as starting points in the quest for inventor knowledge and experience. Although the barrier to entry as an inventor is high, success can be achieved by those with insight, creativity, and perseverance.

CONCLUSION

Despite the economic and legal impediments facing IP development in the current marketplace, many important innovations and technologic breakthroughs within medicine are the result of independent inventors. These independent inventors play a unique and vital role towards IP development in medical imaging and information technology through their practical first-hand experience, "out of the box" mentality, and proactive perspective. They are not restricted by many of the traditional constraints existing within an industry including the incremental approach to product development, internal politics, and a short-term focus on return on investment (ROI). The traditional paradigm of industry-sponsored R&D may be better served through the creation of a more collaborative approach of "outsourcing innovation", thereby creating a synergy between independent inventors and industry sponsors. In the end, innovation can be better served by creating an atmosphere for open competition, creativity, and accountability.

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