GUEST EDITORIAL

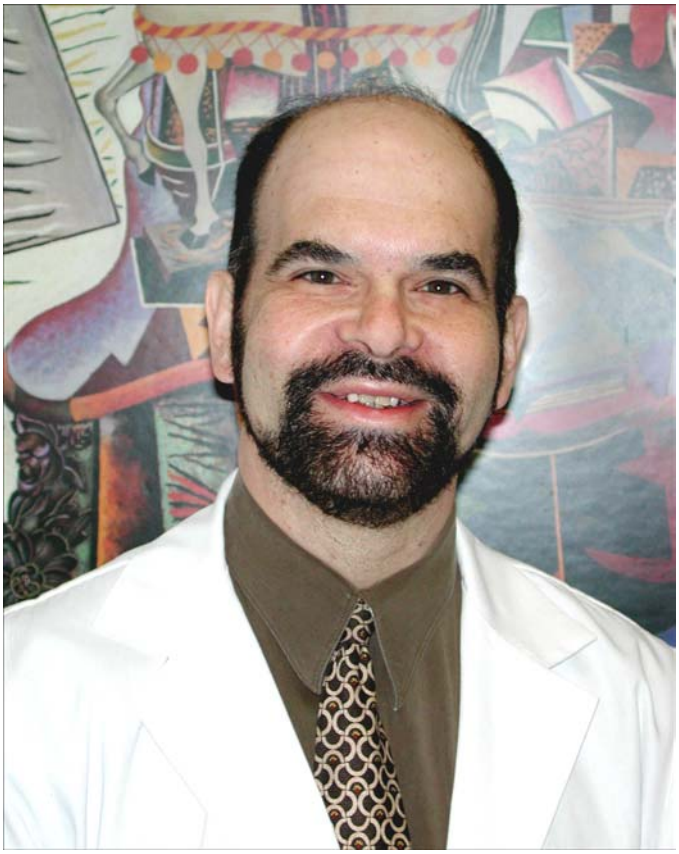
Technology transfer in rehabilitation: A personal account

INTRODUCTION

Technology transfer is the spread and adoption of inventions and techniques from one discipline to another or one sector of the economy to another [1]. Technology transfer between university and industry has become critically significant since World War II. During the 1950s, inventions created from public funding went directly into the public domain (e.g., polio vaccine). However, federal legislation during the 1980s created, for the first time, strong incentives for universities to acquire and hold patents. The intent was to promote commercialization of grant-funded innovations for the public good [2].

With federal and state governments as catalysts, there is now a closer interaction than ever between universities and the private sector, a phenomenon that has met with praise and some concern [3–5]. The concern is that the profit motive and confidentiality will limit the free expression of ideas that makes academia a compelling place to teach and practice. On the other hand, a close relationship between universities and industry, with appropriate diligence, creates opportunities for both [6].

Within rehabilitation medicine itself, technology transfer is problematic. In the rehabilitation unit, we see many of the same devices, weights, mats, resting foot splints, and wheelchairs that were used a generation or two ago. We know all too well that technology can confuse patients and that "simple is best." However, some of the most innovative ideas (or products) for assist devices, pressure mapping, exercise therapeutics, biofeedback, "intelligent" prosthetics, virtual reality-based therapeutics, and functional electrical stimulation have yet to meaningfully penetrate the market for the benefit of our patients. This commentary defines the challenge of rehabilitation technology transfer and touches on practical solutions.



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GENERAL GUIDELINES OF REHABILITATION TECHNOLOGY TRANSFER

Physical medicine and rehabilitation as in other areas of medicine has four stages: *idea, invention, development, and commercialization*. (My personal experience in transfer of technology is outlined later in this commentary.) Commercialization of a medical product (or a consumer product) is market-driven, not technology-driven. This critical point is often

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overlooked. Fortunately, marketing resources are available for rehabilitation-oriented clinicians, scientists, and entrepreneurs [7–10]. In addition, Pressman presents an algorithm to determine the marketability of an invention [11]. For commercial success, the five P's must all be "right": production, price, position (the product's place in the market), promotion, and perseverance.

Creative Process and Idea Formation

It is unclear how the inventive "leap" occurs. It might occur at the interface between two dissimilar fields (e.g., electrical engineering and medicine) that creates a unique solution to a problem seen in routine clinical encounters. The creative inventive process usually involves "out of the box" thinking and can be rewarding unto itself [11–18].

Invention: The Patent Process

Once it is clear that an idea is truly unique, the next step is to patent it. To determine this, the inventor or counsel should conduct a patent search. (Note that computer patent searches go back to 1976 only and thus are incomplete except for high-tech inventions.) The goal of the patent search is to determine if the concept is novel and "unobvious." "Unobvious" is an arcane term used in patent law that means that somebody "skilled in the art" and who knows all articles, references, and patents related to a product or process could not conclude that the concept is obvious. The introduction to the patent application must "knock" the prior art [11]. It is preferable that an "embodiment" be "reduced to practice" (i.e., a prototype created), although a prototype is not legally required for patent submission. In the patent application, detailed illustrations of the invention are included and, if appropriate, quantitative data. The "claims" that define the intellectual real estate form the most important part of a patent and should be written by experienced lawyers. Patent acceptance is no guarantee of commercial success: Only 1 out of 10 patents makes money for the owners [11].

Inventor's Rights

In my opinion, an empowered inventor is an invention's best advocate. Technology transfer offices (TTOs), with a huge docket of technologies to commercialize, tend to focus on the biggest potential market items, which are probably not rehabilitation technologies. Ironically, TTOs differ in the amount of leeway they allow the academic inventor to promote an invention independently. An inventor who is employed by a small or large entity should retain individual legal counsel [14], especially if the projected commercial value of the invention is high, if it is developed without financial support, and if the individual is the sole inventor. Contrary to popular belief, it is not true that if "you think up something in the shower" (or anywhere else outside of work) that it is automatically the property of your employer. In the case of inventor-university disputes, in most regions of the United States, the law favors the academic inventor.* (Also see my personal account, outlined later.)

Disclosure

The inventor must do his or her homework to develop a responsible, empowered approach to disclosure. Disclosure is an ongoing process that involves the department chairman, TTO and, if necessary, the Conflict of Interest Committee. This is especially important if the company in which the academic inventor owns a significant equity interest funds the academic research or vice versa. The university might prohibit such activities.

Development: Licensing Versus Entrepreneurship

If disclosure to the university is advantageous and prudent, the TTO develops an invention docket. The TTO, as part if its "due diligence," analyzes the marketability of the invention. If this analysis is favorable, the TTO promotes the invention among prospective companies and attempts to negotiate a license. A license typically returns less than 10 percent of the sales revenue to the university, with portions of the 10 percent going to the university, the department, and the inventor's laboratory. Licensing may be the best option for an invention readily developed into a single or simple product or process.

*Personal communication with David Pressman author of "Patent It Yourself."

Development: Starting a Business

If the technology is especially promising and has too many valuable uses or potential products for a single license, small business formation with or without faculty entrepreneurship may be appropriate. (Faculty entrepreneurship is defined as the faculty member taking the leadership role in forming the business.) Taking this approach also may depend on the attitude and support of the organizational TTO.

An enlightened approach to faculty entrepreneurship is embodied in the Cooperative Research and Development Agreement (CRADA) [15]. Employed at Department of Veteran's Affairs (VA) Medical Centers, the CRADA provides early stage businesses (and faculty entrepreneurs) access to VA facilities, personnel, and equipment for development projects, as long as funds are provided by the small business. The small business retains exclusive license to inventions and improvements.

Small business formation is a complex topic beyond the scope of this commentary, filled with rewards and pitfalls for the academic inventor [16]. To retain a faculty position, the academic inventor needs to select a management team. Selecting the right people can be the most difficult and important part of business formation. The management team should have the utmost integrity, professionalism, and proven track record. The members are either directly known to the inventor or are known through trusted intermediates (e.g., consul). Beware of consultants who will work only for high hourly fees: Professionals that truly recognize the potential of a robust new technology are willing to work for "future consideration." The faculty entrepreneur should clearly understand his or her role outside of the management team and be willing to yield both management prerogatives and equity to create incentives for the team.

Development: Funding and Small Business Grant Programs

The importance of small business in rehabilitation technology development cannot be underestimated. The federal government funds small business research and development through the Small Business Innovative Research/Small Business Technology Transfer (SBIR/STTR) programs. These programs are typically more accessible than traditional National Institutes of Health (NIH) grant funding mechanisms (e.g., R01 mechanism), because the government is mandated to promote small business. The SBIR promotes small business commercialization, and the STTR develops partnerships between universities and small business [7]. In 2001, there were 4615 SBIR awards totaling $1,158,496,872 and 330 STTR awards totaling $62,990,953. The application process is detailed on the web site [7].

Development: Building Partnerships

There are many university centers whose mission is to bring rehabilitation ideas forward through invention to technology development. If the inventor does not have access to a TTO, the Technology Transfer Research and Evaluation Program (T^2RERC) at the University of Buffalo might be helpful [8]. T^2RERC (funded by the National Institute on Disability and Rehabilitation Research [NIDRR]) acts as a neutral intermediary to partner inventors with entities (i.e., existing companies) that can fund and/or develop the technology.

The purpose of the STTR grant mechanism is to partner a university with small business. For example, a company that markets rehabilitation-related products (Chattanooga Group, Hixson, Tennessee) has partnered with the University of Pennsylvania on an STTR grant for which I am the principal investigator. The principal investigator has designated the university (subcontractor) as the research and development arm of the company (grant recipient) for a grant investigating the role of electrotherapy on ischemic wound healing [17].

Development and Commercialization: Making It Through the "Valley of Death"

The transformation of a technology into a product is the trickiest step on the technology transfer stepladder. This transformation is aptly termed the "valley of death," because few attempts at product development survive the journey [8]. Since products are market-driven, market research must confirm with reasonable certainty that projected revenue will recoup investment dollars. This expensive process involves

engineering and clinical feasibility studies, industrial and ergonomic design processes, and a succession of prototypes. Once a final product is rendered, it must be manufactured in bulk, requiring tooling and outsourcing decisions. Crossing the "valley of death" requires money, persistence, and a compelling business plan. Business plans are a formal means to argue that an untested product will be successful [16].

A critical step in medical (and rehabilitation) device development is garnering Food and Drug Administration (FDA) approval. The FDA considers safety and efficacy and, from these factors, approves product labeling. To render truth from clinical trial data, FDA stipulates exactly how clinical trials are managed [18]. This process is costly (i.e., roughly $1,000 per patient involved in a Phase II clinical trial of a rehabilitation device [17]). The SBIR/STTR mechanism can be invaluable in funding this endeavor.

A bit of good news: Rehabilitation development companies can avoid the most rigorous FDA regulatory barriers by showing "substantial equivalence" of a product under development to a product marketed before 1976. This is known as the "510k provision" [19]. The 510k provisions apply to most physical medicine devices, including assist devices, biofeedback, ultrasonography, diathermy, and electrotherapy. Other very innovative and invasive products (e.g., iBOT advanced mobility device—dynamic balance wheelchair [20]) require full premarket approval (PMA) before they are launched.

Perhaps the most important (and one of the least well understood) regulatory barrier to commercialization of a novel rehabilitation product is obtaining insurance reimbursement. The Medicare Coverage Advisory Committee considers reimbursement for very expensive, novel technologies at the national level. However, regional carriers (in this case Durable Medical Equipment [DME] Regional Carriers [DMERC]) consider reimbursement decisions on "lower cost" technologies (i.e., most rehabilitation products). An important example of rehabilitation technology is DME. Medicare defines DME by the following criteria: (1) can withstand repeated use, (2) primarily serves a medical purpose, (3) is generally not useful to a person in the absence of an illness or injury, and (4) is appropriate for use in the home. It is ironic but consistent with the DME definition that exercise equipment of any type is NOT reimbursed by third-party payers.

As confusing as Medicare DME benefits appear, they are actually broader than most commercial insurers. Commercial insurers have more relatively limited DME benefits with high out-of-pocket costs. Therefore, novel rehabilitation products have quite a difficult time getting reimbursed in the world of managed care, no matter how useful or functional. Despite all the challenges, any examples of rehabilitation technologies have become revenue-generating products [9]. Examples include intrathecal Baclofen pumps, advanced material prosthetics, and cognitive software.

BARRIERS TO COMMERCIALIZATION OF REHABILITATION TECHNOLOGY AND HOW BARRIERS CAN BE OVERCOME

Problem

One of the core challenges with rehabilitation technology (e.g., modalities) is that these treatments have been available for decades. Long-term use assures that they are either not patentable or the patents have expired. Because there is no protected market moving forward, businesses may have considerable difficulty finding investment for new commercial uses.

Solution

A patentable improvement on an existing modality would be a highly desirable result of technological or product development (e.g., through an SBIR/STTR grant) because it would help persuade the private sector to invest in a new (protected) market opportunity.

Problem

Many or most rehabilitation technologies have small niche markets within the field. Marketing analysis that assures purchase of 1,000 to 5,000 units a year of even a "medium tech" product would require a high markup. If the product is considered

DME and reimbursement prospects are not favorable, a market might not exist for a medically useful and robust device. Unfortunately, small niche markets tend to equal low profits.

Solution

In developing a rehabilitation technology, the rehabilitation entrepreneur and/or industrial partner might consider developing rehabilitation technologies into products outside medicine (e.g., sports) to establish quick revenue to renegotiate the reimbursement conundrum at a later date with a larger war chest.

Problem

The physiatrist or inventor is only one of hundreds of deserving academic professionals of many fields with a novel idea in search of patent advice and development funds.

Solution

The university looks out for its own best interest and so should you. With your own best interest in mind and heart, look at all sides of the issue, seek outside advice, and then proceed.

A PERSONAL NARRATIVE OF TECHNOLOGY TRANSFER

As an example of "how to proceed," I offer a brief summary of my personal experience in technology transfer: From *idea*, to *invention* of a technology (force-sensing fabric), to *development* of a product (Isopad™ Muscle Reeducation Device). *Commercialization* of the product is pending. The process has taken, so far, more than a decade:

1. 1989: In residency (PGY-2), I applied simple force sensors to heels of patient with sensory ataxia, which markedly improved gait.
2. I began a study of the sensory feedback augmentation.
3. 1990: Patent search conducted by law firm for force transducers used in limb-load monitors showed that monitors in literature are unwieldy or have not been widely commercialized.
4. 1991: I used a highly resilient polyurethane foam—PPT—to create an "ideal" capacitance transducer.
5. Created inventor's notebook (see *Patent It Yourself* [11],) documenting all experiments, construction techniques, and performance quantification.
6. Conducted all invention activity on own time and at own expense.
7. Distilled 400-page notebook to 50 summary pages and had each page signed by two individuals, with notary seal at end of full notebook.
8. 1992: I wrote a patent application, which was edited by a legal team and used by the team to write the claims.
9. Legal team examined patent policy of training institution and expressed an opinion that no disclosure was necessary.
10. 1995: I (as the inventor) received patent approval [21].
11. 1996: I (as the inventor) created a company to develop the technology into products.
12. Administrator at the office of technology transfer at inventor's university advised licensure rather than entrepreneurship.
13. Conflict of interest committee of university allowed me as the inventor to set up a small business entity.
14. 1996–2000: I (as the inventor) hired a management team, selected a board of directors, and retained a legal team.
15. 1997: As part of "due diligence," the agency funding the business required disclosure of core patent to original training institution [21], which claimed ownership of patent.
16. Institution abrogated claim to invention after receiving 400 pages of documentation and having discussion with inventor's counsel.
17. 1998: Inventor's current university abrogated claim to "improvement" on core patent after negotiation.
18. 1999–2002: Small business obtained NIH SBIR grants (SBIR Phases I and II) to develop a product for therapeutic exercise and completed trials [22].
19. 1999–2001: Product (Isopad™) developed by electrical engineer with input from industrial

design firm, product development company, and rehabilitation steering committee.

20. 2002: Commercialization decisions for this product awaited results of clinical trial.
21. Raised additional investment (private) for application of technology outside medical field in anticipation of near-term revenues required for survival of company.

CONCLUSION

Technology transfer in rehabilitation medicine poses many challenges in terms of *idea, invention* (i.e., patenting), *development,* and *commercialization* (i.e., business planning, funding, engineering development, clinical testing, and breaching regulatory barriers). To walk through this "valley of death" requires focus and persistence. The empowered inventor is the invention's best advocate. Partnerships are required—Choose them wisely. This commentary leans toward entrepreneurship. Most rehabilitation professionals will, for very good reasons (e.g., maintain balance between professional and personal life), prefer licensing. Either way, seek unconventional funding sources and solutions to conceive, develop, and commercialize rehabilitation products for the 21st century.

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