

Physician-Industry Cooperation In The Medical Device Industry

When physician-inventors team up with industry, is it collaborative innovation or conflict of interest?

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ABSTRACT: Anecdotal evidence suggests that innovative medical devices often arise from physicians' inventive activity, but no studies have documented the extent of such physician-engaged innovation. This paper uses patent data and the American Medical Association Physician Masterfile to provide evidence that physicians contribute to medical device innovation, accounting for almost 20 percent of approximately 26,000 medical device patents filed in the United States during 1990–1996. Moreover, two measures indicate that physician patents had more influence on subsequent inventive activity than nonphysician patents. This finding supports the maintenance of an open environment for physician-industry collaboration in the medical device discovery process. [*Health Affairs* 27, no. 6 (2008): 1532–1543; 10.1377/hlthaff.27.6.1532]

THERE IS CONSIDERABLE CONTROVERSY over relationships between medical device companies and practicing physicians. Media outlets have recently highlighted conflicts of interest that can arise from close collaboration between physicians and medical device companies.¹ In particular, concerns have been raised about physicians' financial conflicts of interest in recruiting patients to clinical trials and in reporting results of clinical testing to the medical community.² Critics worry that payments by medical device companies to practicing physicians will influence their decisions about which devices to use and how to document patient outcomes and, in turn, will compromise patients' welfare.

By contrast, device firms and physicians that work with them argue that the corporate relationships are essential to device innovation. In this view, physicians provide essential knowledge of technology and medical practice that become in-

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corporated into new devices. Involvement in activities such as clinical trials and testing is one of the means by which physicians can both learn about new technology and pass information about technology to commercializing companies.

This debate requires data concerning the extent to which physician-industry collaboration contributes to technology invention and development. Anecdotal evidence suggests that physicians often play key innovative roles in medical devices.³ However, little systematic evidence exists. If, in fact, physicians rarely contribute to device innovation, then policymakers may want to create strict barriers to physician-industry interaction to limit conflicts of interest. Alternatively, if physician-led invention is common, then an approach that supports physician-industry interaction while mitigating concerns about conflicts of interest may be required. This paper helps document the role of physicians in the medical device discovery process.

Managing Medical Device Innovation

The medical device sector is highly research-intensive. Medical device companies spend about 9–11 percent of sales on research and development (R&D), second only to the pharmaceutical sector and four times the average for the manufacturing sector as a whole.⁴ Small companies in this industry (those with less than \$5 million in revenue), including many start-ups and highly innovative firms, spend 343 percent of revenue on R&D, on average.⁵ The leading medical device companies derive the majority of their revenues from products that are less than two years old, as a result of competition from fast imitators.⁶ The life cycle for new products in the medical device industry lasts about eighteen months, making new product innovations crucial for firms.⁷ Their key challenge is to conceive new ideas, anticipate market demand, manage product development, gain regulatory approval, and encourage adoption of new technologies and new generations of existing technologies.

■ **Physicians' contribution to the invention process.** Firms that develop strategies to detect and acquire knowledge residing outside the firm have the most success in maintaining their innovative edge.⁸ In the medical device industry, practicing doctors represent an important source of external knowledge regarding unmet needs, customers' preferences, and potential opportunities for either refining existing products or creating novel products that would be well received by other doctors and medical professionals.⁹

Physicians may contribute directly to the innovation process by inventing medical devices themselves. This kind of "user innovation" has been documented in diverse settings such as scientific instruments, snowboards, and software.¹⁰ In the device industry, famed physician-inventors such as Thomas Fogarty have patented numerous inventions and founded multiple companies. Doctors often have the best knowledge about unmet clinical needs and the clearest sense of the most feasible solution to a particular problem, which provides unique insights about mar-

ket needs, product modifications, and new products. Doctors' knowledge is derived from using the device—they know what is problematic, which improvements are most critical, and which solutions are preferable from the perspective of the end user. The depth of this knowledge is based on the experiences of the doctor and may be difficult to convey to industry researchers without the benefit of close communication and a relationship that develops trust.

■ **Physicians' manufacturing and marketing functions.** Physicians who invent new devices or modify existing devices typically do not manufacture and market the devices themselves.¹¹ Although there are some examples of physician-inventors who became entrepreneurs and started their own companies to bring their inventions to market, most physicians focus on their job as doctors and lack the business and regulatory knowledge required to manufacture and market a device. Instead, most physicians with innovative medical device ideas transfer their ideas to medical device companies, often after patenting an invention that they then license for development, approval, and marketing. Such licenses often involve continuing engagement with the company, so that the physician's knowledge can continue to help shape the development of the new technology.

A Snapshot Of Physician Innovation

■ **Data sources.** To evaluate the role of physician-inventors in the medical device industry, we used data from the American Medical Association (AMA) Physician Masterfile and the National Bureau of Economic Research (NBER) patent database.¹² Bringing these data sets together, we used an algorithm to match the names of doctors in the AMA data to inventors' names in the patent data, using city and state location information from both files to eliminate potential false matches.¹³ This approach allowed us to identify which medical device patents had at least one inventor who was a licensed physician.¹⁴

The average number of inventors on medical device patents in our sample was 1.98, so the presence of one doctor represents a major contributor to the invention.¹⁵ Note that inventor status on a patent involves legal rights and responsibilities and determines ownership of the patent. Incorrect attribution of patent inventorship may invalidate a patent.¹⁶ Thus, inventorship is likely to represent the actual contributions of inventors to the invention.

Of course, this approach provides only a partial picture of physicians' involvement in device innovation. Many innovations are not patented and so will not appear in the data. Nonetheless, the patenting records provide a meaningful assessment of physician innovation.

■ **Measuring the extent of physician innovation.** To explore the role of physicians' innovation in this context, we sought to answer two questions. First, what is the extent of this innovation in the medical device industry, as measured by patent counts? Second, what is its relative importance? We would have liked to examine the corresponding sales of medical devices invented by doctors, but there is no reli-

“Evidence suggests that doctors are important sources of device innovation and is consistent with other studies of user innovations.”

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able way to match patents to commercialized products. Instead, we focused on the degree to which later inventions referenced a particular invention as a measure of the focal invention's importance in the stream of technological developments, which in turn will affect both corporate sales and patient welfare.

■ **Measuring the impact of physician innovation.** We used two measures of impact. One measure of the importance of a patented innovation involves counting the number of citations it receives in subsequent patents.¹⁷ Much like an influential academic paper, important patents will generate follow-on inventions. These follow-on inventions are legally required to cite patented prior art on which they are based. Being cited by a large number of follow-on inventions indicates that the original invention has been influential in a large number of technological advances. Consistent with this interpretation of patent citations, for example, Manuel Trajtenberg found that the number of citations received was closely associated with independent measures of the social value of computed tomographic (CT) scanner inventions.¹⁸ Researchers often compare the number of citations received by two patents to evaluate which has been more influential.

A second way to measure the impact of a patented invention is to consider the breadth of technological space that it influences. Patents that influence follow-on technologies across a more diverse set of areas have a broader impact. We captured the breadth of citations received with a generality score developed by Trajtenberg and colleagues.¹⁹ The higher the generality score, the more diverse the range of technologies that build upon the original patent.²⁰

To accurately measure both aspects of invention impact, we needed a sampling frame that would allow us to observe a reasonable time period after the technology was patented and during which the follow-on citations could occur. We examined patents granted between 1990 and 1996 to provide an appropriate “post-patent” period (until 2002) over which to assess the impact of the patents.

■ **Number of doctors holding patents.** There were 26,158 patents granted in the nineteen medical device patent classes identified by the U.S. Patent and Trademark Office from 1990 through 1996, which collectively received more than 344,000 citations. Of these medical device patents, 5,051 (19.3 percent) had at least one inventor who was a licensed physician. Hence, nearly one in five of the patented inventions in this field were invented by doctors or with the participation of doctors. Since the patent application process is costly in terms of both time and money, this figure does not include the products of “tinkering” by doctors that never result in patented inventions but do affect medical practice.

These results are the first large-sample evidence of the extent of physician innovation in the medical device industry. This evidence strongly suggests that doctors

are important sources of device innovation and is consistent with other studies of user innovations. For example, Eric von Hippel and colleagues found that 20–80 percent of important innovations in scientific instruments, software, and sports equipment are generated by users.²¹ However, in a tightly regulated, R&D-intensive industry such as medical devices, we were surprised to find that users accounted for such a high percentage of innovations.

■ **Employment of physician inventors.** Consistent with the idea that physician-inventors are often practicing physicians, almost 60 percent of physician-inventors with identified affiliations worked either in a group practice, two-physician practice, or solo practice (Exhibit 1). In addition, sizable portions work in more complex institutional settings that include medical practice, including medical schools, nongovernment hospitals, and a range of other hospital venues. The core point is that practicing physicians in a wide range of U.S. medical settings commonly engage in medical device inventive activity.

■ **Patenting activity by physician specialty.** Physicians from seven specialties generated more than 50 percent of the patents: orthopedic surgeons, general surgeons, and cardiologists make up the largest share of the inventions, followed by anesthesiologists, internists, ophthalmologists, and diagnostic radiologists (Exhibit 2). Although these areas clearly represent much of the inventive activity, there is considerable dispersion of inventive activity across many specialties. These differences likely reflect the size of the fields, the number of unmet clinical needs, and the

EXHIBIT 1
Primary Employment For Physician-Inventors Of Medical Devices, 1990–1996

Employment setting	Percent of sample
Group practice	31
Two-physician practice	4
Self-employed solo practice	24
Medical school	8
Nongovernment hospital	8
Other non-patient care	3
City/county/state hospital	2
Federal government hospital (veterans)	1
Other patient care	1
HMO	0.3
Federal government hospital (U.S. PHS)	0.3
City/county/state other	0.2
Federal government hospital (Army)	0.2
Federal government hospital (Navy)	0.1
No classification	16
All other	<1.0

SOURCE: Authors' calculation.

NOTES: HMO is health maintenance organization. PHS is Public Health Service.

EXHIBIT 2
Specialties Of Physician-Inventors, 1990–1996 Medical Device Inventions

Specialty	Number of patents	Percent physician patents	Cumulative percentage
Orthopedic surgery	587	11.6	11.6
General surgery	487	9.6	21.2
Cardiovascular disease	481	9.5	30.7
Anesthesiology	322	6.4	37.1
Internal medicine	284	5.6	42.7
Ophthalmology	278	5.5	48.2
Diagnostic radiology	230	4.6	52.8
Family medicine	153	3.0	55.8
Plastic surgery	141	2.8	58.6
Gastroenterology	120	2.4	61.0
Emergency medicine	113	2.2	63.2
Urology	116	2.3	65.5
Obstetrics/gynecology	110	2.2	67.7
Neurological surgery	107	2.1	69.8
Vascular surgery	107	2.1	71.9
Thoracic surgery	101	2.0	73.9
Otolaryngology	83	1.6	75.5
Other specialty	76	1.5	77.0
Unspecified	73	1.5	78.5
Dermatology	61	1.2	79.7
General practice	59	1.2	80.9
Psychiatry	56	1.1	82.0
Pediatrics	57	1.1	83.1
Gynecology	56	1.1	84.2
Hand surgery	51	1.0	85.2
Pulmonary diseases	48	1.0	86.2
Radiology	48	1.0	87.2
Neurology	41	0.8	88.0
Anatomic/clinical pathology	34	0.7	88.7

SOURCE: Authors' calculation.

NOTES: The exhibit reports sources of 4,480 of the 5,051 doctor patents (88.7 percent of the total); in the interest of space, we omitted specialties with less than 0.7 percent of the total. "Percent physician patents" is the percentage of all physician-invented patents in the sample that fall into each specialty category.

technological opportunities in these specialties.

■ **Patents' importance.** Based on a comparison of the mean number of citations received and the generality of these citations, we found that physician patents both received more citations (15.2 versus 12.7) and had higher generality scores (0.41 versus 0.39) than corporate inventions, with both differences statistically significant at better than the 1 percent level (Exhibit 3).²² In addition, comparing the mean number of citations from follow-on inventions that were developed by corporations indicates that doctors also received more citations from follow-on industry-generated inventions (12.5 versus 10.5).²³

EXHIBIT 3
Sample Summary Statistics For Physician And Nonphysician Medical Device Inventions: Means And Test For Difference Of Means

Variable	Full sample	Physician inventions	Nonphysician inventions	Difference (physician: nonphysician)
Number of cites received	13.16	15.23	12.66	2.57***
Number of industry cites received	10.88	12.55	10.47	2.07***
Generality of citations received ^a	0.39	0.41	0.39	0.02***

SOURCE: Authors' calculation.

NOTES: The means of generality for the full sample and nonphysician subsample appear the same because of rounding. N = 26,158 (full sample); n = 5,051 (physician); n = 21,007 (nonphysician).

^aThe higher the generality score, the more diverse the technologies that have built upon the original patent.

***p < 0.01

Discussion

Our results provide evidence that physicians play an important role in the medical device innovation process. Physicians contributed to almost 20 percent of the patents in this sample of more than 26,000 patents. Furthermore, physician patents were more highly cited by subsequent patents than nonphysician patents and had higher generality scores representing the breadth of the invention. The main conclusion is that doctor innovations in the medical device industry are important for device innovation in the United States.²⁴

■ **Quantifying the value of impact.** It is useful to place the impact results into context. What does an additional citation really signify? Attempts to quantify the value of important inventions, as represented by the number of citations received, provides some indication of the magnitude of our results. In analyses of the relationship between the average number of citations received by a firm's patents and the firm's market value, Bronwyn Hall and colleagues found that one additional citation increased the firm's market value by more than 3 percent.²⁵ This is consistent with the "million dollar" value per citation suggested by Dietmar Harhoff and colleagues as well as findings in other studies of patent indicators.²⁶ These findings suggest that a difference of even one citation indicates much difference between inventions. Our findings suggest that physician-generated inventions receive on average 2.5 more citations than other medical device inventions—a major difference in the value of these inventions.

■ **Study limitations.** There are several limitations to this analysis. First, although we constructed a rigorous matching algorithm based on geographic characteristics common to our physician and invention data sets to identify physician-inventors of patents, we could not ensure that the match was fully accurate, especially for common names. Second, our measures of impact of physicians' invention are indirect measures, because we could not be sure which patents were incorporated into mar-

keted products. Finally, it is impossible to know from the patent data if and when patents were licensed. Therefore, we could not evaluate the frequency or performance of physician inventions licensed by medical device companies. Nonetheless, the results provide robust evidence that physicians are active medical device patenters and that their patents are common components of subsequent innovations.

Policy Implications And Recommendations

Patients benefit from progress in medical science through the creation of innovative goods and services that bring advances to the clinical realm. Medical devices are one class of products that can accomplish this goal. The life cycle of device innovation, as for other new products, involves three steps: discovery, development, and dissemination. This study provides evidence that physicians are deeply engaged in the discovery stage, where patenting is most common. Indeed, the results undoubtedly understate physicians' engagement in discovery, because many novel ideas are not patented. The Bayh-Dole Act was enacted in part to stimulate this process by encouraging research in academic settings.²⁷

Physicians' engagement in device invention includes both academic and, more frequently, nonacademic settings. Frankly, we were surprised by the degree of innovation among physicians in nonacademic settings. This innovation seems to occur without many of the support structures and incentives available in academic settings. Although this finding merits further research to characterize this innovation, our findings suggest that physicians' involvement in medical device innovation goes well beyond traditional research settings.

■ **Support physician-led discovery outside academe.** One policy recommendation, therefore, is to create initiatives that support physician-led discovery outside traditional academic settings. Such initiatives could include small-scale seed funding for inventive projects in clinical practices and nonteaching hospitals or expanded support for physician-inventors bringing ideas through the "valley of death" between discovery and commercialization. These initiatives, which could be managed by the National Institutes of Health or other institutions, could yield sizable payoffs by expanding the scope of traditional settings for device innovation.

■ **Facilitate physicians' knowledge transfer.** The study also has implications beyond the discovery stage. The literature on the management of innovation has long demonstrated the value of connecting people who are engaged in discovery to subsequent steps of development and dissemination to facilitate knowledge transfer throughout the innovation cycle.²⁸ By inference, therefore, this study suggests that there are benefits to allowing and encouraging physicians to engage in development and dissemination, which typically involves collaboration with commercializing firms, to facilitate innovative activity that will benefit patients. Some of these commercial collaborations will involve the patenting physicians, and others will involve other physicians with insights that contribute to effective development and usage. In either case, physicians' insights about inventive opportunities often make key

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contributions to commercialization of successful medical device innovations.

■ **Limit potential conflicts of interest.** Nonetheless, with opportunities for physicians to engage in innovation come potential conflicts of interest that can harm patients’ welfare by biasing physicians’ decisions.²⁹ That is, the paradigm of advancing science and patient welfare through physician-engaged product innovation raises the potential for conflicts of interest on the part of physicians, their institutions, and their industry sponsors.

Avoid absolute barriers to physician-industry collaboration. One approach to limiting conflicts of interest would be to create barriers to collaboration among physicians and corporations in activities such as product testing and clinical trials. However, by extension, our study suggests that strict limits on collaboration would inhibit the flow of ideas from physician-led discovery through development and into medical practice.

Thus, a second policy implication of the study is that regulations should avoid absolute barriers to physicians’ engagement in corporate development activities. Instead, policies should take a more nuanced approach to managing potential conflicts of interest. That is, public policies need to maintain the benefits of facilitating physician innovation while limiting the potential for conflicts of interests on the part of physicians and industry. Industry also needs to be supported in its commitment to continue to engage physicians in these efforts.

Increase the scope of congressional transparency requirements. Bias arising from conflicts of interest will be most pronounced when there is a lack of transparency about the roles that physicians play in a given stage of the innovation cycle. The lack of transparency has been highlighted by reports in the lay and medical press illustrating examples of physicians’ serving multiple roles in this process without informing others.³⁰ Hence, a key element of public policy is to ensure reliable transparency of relationships between physicians and corporate sponsors.

Congress is considering legislation to assure the public of transparency in physicians’ relationships with industry. Several proposals for “sunshine” laws would require disclosure of financial relationships between physicians and product manufacturers. These requirements would augment existing financial disclosure requirements that exist in continuing medical education, publication in the peer-reviewed literature, and clinical investigation.³¹

Our findings suggest that physicians are active in medical device innovation as early as the discovery stage. In turn, transparency should apply from the beginning of the innovative life cycle. Hence, a third policy implication of the study is that sunshine requirements should apply to physicians’ engagement in commercial activity at the discovery stage, as well as at subsequent development and dis-

semination stages.

Mandate audit mechanisms for financial transparency. Finally, for such disclosure requirements to be effective at any stage of the innovation life cycle, there will need to be audit mechanisms that compare disclosures with company data and highlight discrepancies between physicians and industry (of course, legitimate differences may exist between these sources based on differences in accounting and reporting methods adopted by all parties). To ensure that these provisions include private firms that could have sizable physician investment, the sunshine provisions should relate to all firms that have products approved for marketing by the U.S. Food and Drug Administration or for which there is a provision for payment under Medicare or Medicaid.

EMPIRICAL EVIDENCE SUPPORTS the proposition that physicians are important contributors to medical device innovation. This evidence supports the need to foster the role of physicians in technology discovery and to be mindful of this role as policymakers consider conflict-of-interest policies that affect collaboration between physicians and corporations. An R&D climate that fosters physicians' participation in the discovery process may produce more and better medical devices than a climate that discourages physicians from participating. The public would benefit, however, from efforts to promote reliable transparency in physician-corporate relationships throughout the innovation life cycle.

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 Kevin Schulman has made available a detailed listing of financial disclosures; it is available online at <http://content.healthaffairs.org/cgi/content/full/27/6/1532/DC1>.

NOTES

1. R. Abelson, "Financial Ties Are Cited as Issue in Spine Study," *New York Times*, 30 January 2008.
2. Dennis Thompson describes a medical conflict of interest as "a set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)." D.F. Thompson, "Understanding Financial Conflicts of Interest," *New England Journal of Medicine* 329, no. 8 (1993): 573-576.
3. E.B. Roberts, "Technological Innovation and Medical Devices," in *New Medical Devices: Invention, Development, and Use*, ed. K.B. Ekelman (Washington: National Academies Press, 1988), 35-51.
4. AdvaMed, *The Medical Technology Industry at a Glance, 2004*, <http://www.advamed.org/NR/rdonlyres/0A261055-827C-4CC6-80B6-CC2D8FA04A33/0/ChartbookSept2004.pdf> (accessed 1 August 2008); and Centers for Medicare and Medicaid Services, "Health Care Industry Market Update: Medical Devices and Supplies," 5 December 2003, <http://www.cms.hhs.gov/CapMarketUpdates/Downloads/hcimul20503.pdf> (accessed 1 August 2008).
5. AdvaMed, *The Medical Technology Industry at a Glance*.
6. E.A. Halm and A.C. Gelijns, "An Introduction to the Changing Economics of Technological Innovation in Medicine," in *The Changing Economics of Medical Technology*, ed. A.C. Gelijns and E.A. Halm (Washington: National Academies Press, 1991), 1-18.
7. S. Bell, "Investing in Tomorrow: Gaining a Competitive Edge in Outsourcing Your R&D," *Medical Product Outsourcing*, Jan/Feb 2006, <http://www.mpo-mag.com/articles/2006/01/investing-in-tomorrow> (accessed 17 September 2008).
8. I. Cockburn and R. Henderson, "Absorptive Capacity, Coauthoring Behavior, and the Organization of Research in Drug Discovery," *Journal of Industrial Economics* 46, no. 2 (1998): 157-182; and W.M. Cohen and D.A.

- Levinthal, "Absorptive Capacity: A New Perspective on Learning and Innovation," *Administrative Science Quarterly* 35, no. 1 (1990): 128-152.
9. Studies have long documented the role of physicians in medical product use and diffusion. See, for instance, J.S. Coleman, E. Katz, and H. Menzel, *Medical Innovation: A Diffusion Study* (Indianapolis: Bobbs-Merrill Co., 1966); and Roberts, "Technological Innovation and Medical Devices."
 10. E. von Hippel, "The Dominant Role of Users in the Scientific Instrument Innovation Process," *Research Policy* 5, no. 3 (1976): 212-239; E. von Hippel, "Lead Users: A Source of Novel Product Concepts," *Management Science* 32, no. 7 (1986): 791-805; and E. von Hippel, "Economics of Product Development by Users: The Impact of 'Sticky' Local Information," *Management Science* 44, no. 5 (1998): 629-644.
 11. J.S. Grossman, *Innovative Doctoring: Solutions Lie within Us* (Self-published, 2006).
 12. We focus on the nineteen U.S. Patent and Trademark Office (USPTO) classes that contain medical device innovations, as determined by the USPTO.
 13. For further details on the matching process, see A.K. Chatterji and K. Fabrizio, "Professional Users as a Source of Innovation: Physician Innovation in the Medical Device Industry" (Working Paper, Duke University, Durham, North Carolina, 2008).
 14. Inventor status on a patent confers an individual with a legal right to exclude others from use. See B.H. Hall and R.H. Ziedonis, "The Patent Paradox Revisited: An Empirical Study of Patenting in the U.S. Semiconductor Industry, 1979-95," *RAND Journal of Economics* 32, no. 1 (2001): 101-128; and A. Mossoff, "Rethinking the Development of Patents: An Intellectual History, 1550-1880," *Hastings Law Journal* 52 (2001): 1255-1322. Therefore, patent inventors are not added superfluously.
 15. The number of inventors on inventions including at least one physician range from one to twelve. The number of inventors on other patents in the sample range from one to twenty. Of the physician patents, 43 percent include only the physician as a solo inventor, 27 percent include the physician and one other inventor, and 16 percent include three inventors. The great majority (88 percent) of inventions with a physician-inventor include only one physician-inventor, while an additional 9 percent include two physicians, and less than 3 percent include more than two physicians. We examined the possibility that physicians' solo-invented patents might look quite different from those inventions with a physician as part of an inventing team. Controlling for the effect of having at least one physician-inventor on a patent, results suggest no additional difference in the number of citations received (importance) or number of industry citations received for patents on which the physician is a solo inventor or for patents that contain multiple inventors who are all physicians.
 16. D.S. Chisum, *Chisum on Patents: A Treatise on the Law of Patentability, Validity, and Infringement* (New York: Bender, 2002), sec. 22.03.
 17. This measure of importance has been used numerous times in the economics of innovation literature and has been shown to be positively related to market value. See B.H. Hall, A. Jaffe, and M. Trajtenberg, "Market Value and Patent Citations," *RAND Journal of Economics* 36, no. 1 (2005): 16-38.
 18. M. Trajtenberg, "A Penny for Your Quotes: Patent Citations and the Value of Innovations," *RAND Journal of Economics* 21, no. 1 (1990): 172.
 19. M. Trajtenberg, R. Henderson, and A. Jaffe, "University versus Corporate Patents: A Window on the Basicness of Invention," *Economics of Innovation and New Technology* 5, no. 1 (1997): 19-50.
 20. For further details on how the generality score is calculated, see Chatterji and Fabrizio, "Professional Users as a Source of Innovation."
 21. E. von Hippel, *The Sources of Innovation* (Oxford: Oxford University Press, 1988). The measure of innovation differs across studies, including patents, products, and major contributions.
 22. Additional analysis found that the differences between physician patents and nonphysician patents are most dramatic among the most highly cited patents. We confirmed these results using regression analysis controlling for year and other patent characteristics, which the authors can provide on request. Send e-mail to ronnie@duke.edu. Chatterji and Fabrizio, "Professional Users as a Source of Innovation," provides further detail concerning these data.
 23. In any such comparison, the noted differences might be partly driven by selection. In our context, differing costs (real or opportunity costs) may generate differing hurdles of expected value of the invention that must be overcome to pursue a patent. If, as a result, physicians have a different propensity to patent their inventions relative to corporations or other individual inventors, then the sets of patented inventions might not be truly comparable. We examined this possible bias in two ways. First, we compared inventions with physician-inventors that were assigned to corporations with other corporate-assigned patents,

and similarly compared noncorporate physician and nonphysician patents. That comparison yielded results very similar to those reported here. Second, we made use of the “primary employment” data for the physician-inventors to examine whether or not physicians who we would expect to incur greater (opportunity and real) costs when pursuing a patent application demonstrate the expected bias in the outcome variables. We did not find such a pattern. These robustness tests give us confidence that the basic differences that we found between physician-generated inventions and other inventions are not driven by selection bias generated by a difference in opportunity costs.

24. It might also be useful to link medical device patents to Food and Drug Administration (FDA)-approved products to provide another view of the importance of physicians in the product development process, but there is no systemic documentation of which patents apply to which medical device products.
25. Hall et al., “Market Value and Patent Citations.”
26. D. Harhoff et al., “Citation Frequency and the Value of Patented Inventions,” *Review of Economics and Statistics* 81, no. 3 (1999): 511–515.
27. *Bayh-Dole Act*, PL 96-517, codified at 35 U.S. Code, secs. 200–212. See also W. Mitchell, “Using Academic Technology: Transfer Methods and Licensing Incidence in the Commercialization of American Diagnostic Imaging Equipment Research, 1954–1988,” *Research Policy* 20, no. 20 (1991): 203–216.
28. J. Jewkes, D. Sawers, and R. Stillerman, *The Sources of Invention* (London: MacMillan, 1958); C. Freeman, *The Economics of Industrial Innovation* (Harmondsworth, U.K.: Penguin, 1974); and C. Varmazis, “Ausiello: More Academy-Industry Collaboration Needed,” 28 July 2008, <http://www.bio-itworld.com/ecliniqua/2008/07/28/ausiello-dia-keynote.html> (accessed 1 August 2008).
29. J.S. Klein, “Stark Laws: Conquering Physician Conflicts of Interest?” *Georgetown Law Journal* 87, no. 2 (1998): 499–529.
30. K.P. Weinfurt et al., “Consistency of Financial Interest Disclosures in the Biomedical Literature: The Case of Coronary Stents,” *PLoS ONE* 3, no. 5 (2008): e2128.
31. Regarding continuing medical education, see Accreditation Council for Continuing Medical Education, “ACCME Standards for Commercial Support: Standards to Ensure the Independence of CME Activities,” http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf (accessed 1 August 2008). Regarding peer-reviewed literature, see International Committee of Medical Journal Editors, “Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication,” October 2007, <http://www.icmje.org> (accessed 1 August 2008). Regarding clinical investigation, see U.S. Food and Drug Administration, “Guidance: Financial Disclosure by Clinical Investigators,” 20 March 2001, <http://www.fda.gov/oc/guidance/financialdis.html> (accessed 1 August 2008).