SPECIAL ARTICLE

The Anatomy of Medical School Patenting

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ABSTRACT

BACKGROUND
Although issues related to patenting by faculty at academic medical centers have been the source of much controversy, there is little systematic evidence of the growth of these activities, their distribution among academic departments, and their relationship to faculty research efforts.

METHODS
We pooled data on medical school faculty, National Institutes of Health (NIH) grant activity, and patenting to examine changes in the propensity to apply for a patent during the period from 1981 through 2000 that was subsequently granted, the distribution of these activities among departments, and the relationships between patenting and variables associated with individual faculty members. These variables included sex, academic degree, years since the last academic degree was earned, patenting by departmental peers, and NIH funding history. In addition to basic descriptive statistics, we estimated Poisson regression models based on the number of patents a faculty member applied for as a function of these variables.

RESULTS
Applications for patents that were subsequently granted per medical school faculty increased dramatically during the period from 1981 through 2000. Although most patenting activity was carried out by faculty members in clinical departments, their rate of patents was low relative to that of faculty members in basic science departments. Regression results showed that persons were more likely to patent if they had recent NIH funding, were male, had Ph.D. degrees, were more experienced faculty members, and worked in departments with higher patenting rates.

CONCLUSIONS
Although the number of patents granted to medical school faculty increased dramatically during this period, patent activity was concentrated among a small number of departments and faculty members. Moreover, persons who had recently received NIH funding were more likely to apply for a patent than those who had not received such funding.

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Over the past quarter century, faculty members at U.S. medical schools increasingly have become involved in a range of commercial activities, including patenting and licensing. The dramatic growth in academic biomedical patenting and licensing has been accompanied by an equally striking growth in controversies and concerns relating to these activities and to academic–industry relationships in the life sciences more generally.[1,2]

One concern relates to the effects of increased academic patenting and licensing activity on the values and culture of medical schools.[3,4] A related concern is that growth in these activities reflects a shift from fundamental to applied research at medical schools.[2] Whereas these issues arise in debates about the effect of patenting on the academy generally, a specific concern regarding academic medical centers is that potential conflicts of interest may arise when clinical researchers obtain patents on therapies they are testing in patients. However, other commentators have cautioned that these criticisms of patenting by academic faculty members and university–industry relationships in academic medicine are misguided and overblown.[5,6]

There are few systematic data regarding the growth of patenting in medical schools, the extent of faculty involvement in patenting, and the characteristics of medical school faculty who patent. Most of the evidence of the participation of biomedical researchers in commercial activities is based on anecdotal reports or cross-sectional survey results.[7] We conducted a systematic, longitudinal analysis of patenting in medical schools with the use of a data set that combines information about all medical school faculty members, patents, and National Institutes of Health (NIH) grants during the period from 1981 through 2000.

METHODS

COLLECTION OF DATA

Our data set is based on three main sources: the Association of American Medical Colleges (AAMC) Faculty Roster, which includes information on active full-time faculty from all medical schools during the period from 1981 through 2000; the NIH Consolidated Grant Application File (CGAF), which provides information on grants awarded, principal investigators and their institutions, and several project characteristics; and the database of patents issued by the U.S. Patent and Trademark Office (USPTO) during the period from 1976 through 2004. The USPTO database contains information on issued patents, the inventors listed on the patents, and the institutions to which they are assigned.

We collected data from the AAMC Faculty Roster on 158,266 faculty members with an M.D. degree, a Ph.D. degree, or a joint M.D.–Ph.D. degree. We also extracted demographic information such as the faculty members' sex, department, and experience (years since the last academic degree had been earned).

Some inaccuracies in the AAMC Faculty Roster data reflected lags in reporting changes in academic appointments. These inaccuracies did not compromise our ability to match faculty members with NIH grant data, since the two data sources included a common set of individual-level identifiers. However, these inaccuracies were an issue in matching faculty members with the patent data for which no such identifiers exist, and our matches were instead based on the faculty member's name and institutional affiliation. For the subgroup of faculty members who were both NIH grantees and patent holders, we found a 1-year lag in recording appointment transitions for 5% of the faculty members and a 2-year lag in recording such transitions for an additional 2% of the faculty members.

We began by matching the AAMC Faculty Roster data to the USPTO data, using information on individual names, institutions, and the timing of patenting. To prevent a compromise of this matching process because of the lags in the reporting of affiliation changes — that is, to avoid false negative results — we identified each faculty member whose name (or variant thereof) appeared in both the AAMC Faculty Roster and the patent database but whose institutional information did not match, and we used information from Web pages, publication history, and patents to determine whether the faculty member was in fact the same person. Similarly, to guard against false positive results, we used such information to determine whether a person with a common name was in fact the same person. Specifically, we paid particular attention to the records containing a last name that was common to five or more faculty members in the AAMC Faculty Roster.

On the basis of these matches, we obtained counts of all awarded patents that were applied

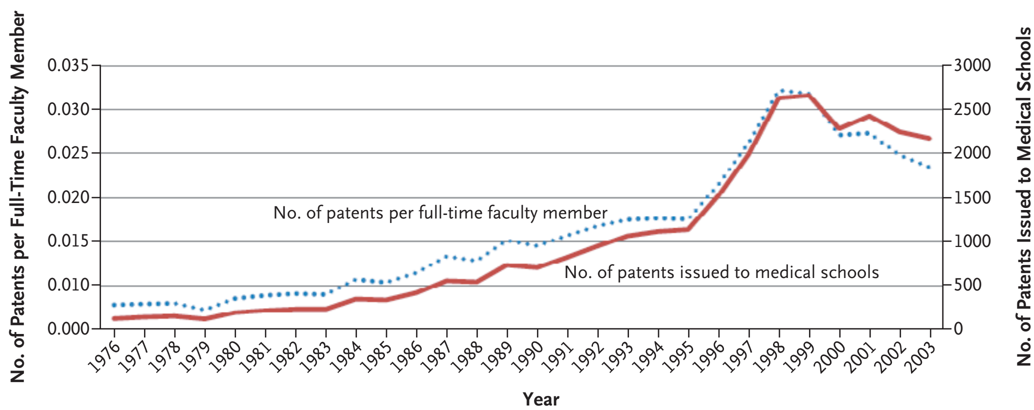

Figure 1. Medical School Patenting, According to Issue Year, from 1976 to 2003.

The solid line shows the increase in the number of patents granted to medical school faculty, from 122 in 1976 to 2175 in 2003 (with a peak of 2664 in 1999). The dashed line shows that this increase was not simply due to the increase in the number of medical school faculty members during this period, since the increase in patents is also evident on a per capita basis.

for during the period from 1981 through 2000 and granted by 2004 to each of the faculty members. We also determined the cumulative number of patents granted to the department with which the person was affiliated.

Finally, we used the unique individual identifiers in the AAMC and CGAF databases to collect information on grants awarded to the medical school faculty members, including data on amounts awarded per year. Because we were interested in grants reflecting individual-level research productivity, we concentrated on individual awards, including research grants, cooperative agreements, research and development contracts, and career awards.

STATISTICAL ANALYSIS

We pooled data on medical school faculty, NIH grant activity, and patenting to examine changes in the propensity to apply for a patent during the period from 1981 through 2000, the distribution of these activities among departments, and the relationships between individual-level patenting and variables associated with individual faculty members, including sex, academic degree, experience (years since the faculty member's last academic degree had been earned), patenting by departmental peers, and history of NIH funding.

In addition to basic descriptive statistics, we used regression modeling to estimate the number of patents that a faculty member would be expected to receive according to the date of the application year of the patent. Since the dependent variable — the number of patents — is a count variable, we estimated Poisson models. Estimates are presented as relative rates, or the effect of a unit change in an explanatory variable on the relative rate of patenting. Coefficients of less than 1 indicate that a variable has a negative effect on patenting, whereas coefficients exceeding 1 indicate a positive effect on patenting.

The first model related patenting to the following factors: the faculty member's years of experience since he or she received the last academic degree and the square of this number of years (to capture variations in the propensity to apply for a patent over the life cycle), variables indicating the type of degree, sex, an indicator variable for each department, and an indicator variable for each year (to capture secular changes in the propensity to patent).

The second model included a set of variables to capture the variation in past research productivity. These variables were the dollar amounts of previous NIH funding received. We deflated these amounts by means of the Biomedical R&D Price Index to adjust for inflation.[8] A cumulative funding variable, the total "stock" of NIH funding, captures both the person's past research intensity and scientific eminence, as determined by the NIH peer-review community. Our model also included 1- and 2-year lagged NIH funding measures. Af-

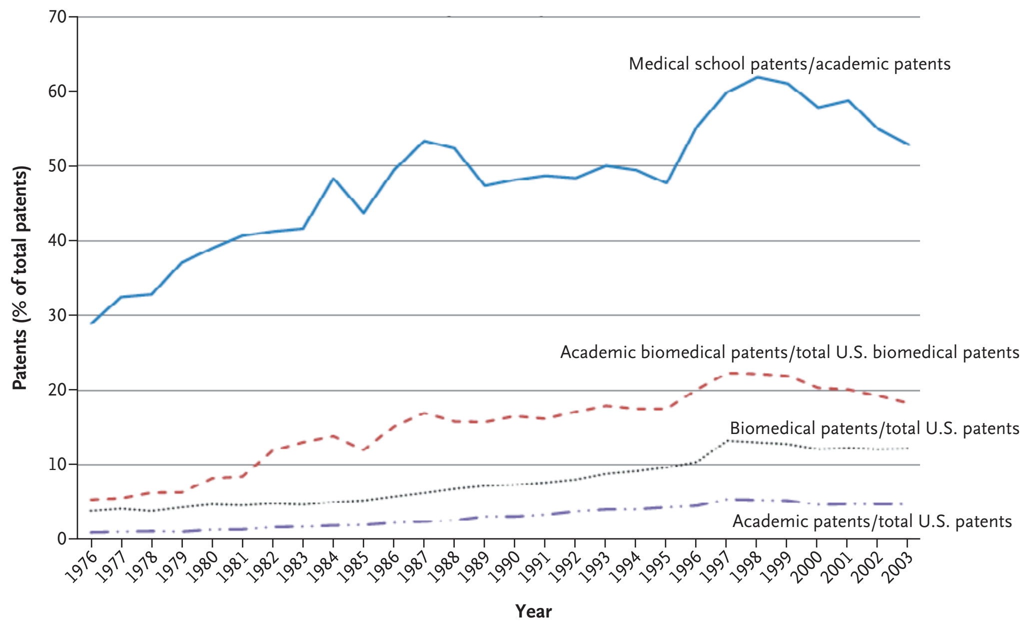

Figure 2. Medical School Patents, Academic Patents, Total Biomedical Patents, and Total Patents, According to Issue Year, from 1976 to 2003.

Patents granted to faculty members of medical schools accounted for an increasing share of all academic patents (from 29% in 1976 to 53% in 2003), even though the share of all domestically assigned patents from universities increased during this period.

ter adjustment for the cumulative stock of NIH funding, these measures captured the effects of recent deviations from the level of funding that would be predicted from a person's history. Although we could not directly measure the effects of departmental "culture" on a person's propensity to apply for a patent, we used the cumulative number of patents granted to the department in which the person worked as a proxy variable.

Because of potential unobserved correlations between the characteristics of individual faculty members and these variables, we also estimated a third model with indicator variables (fixed effects) for each faculty member. The estimates from this model were based solely on changes in the explanatory variables and patenting during a faculty member's career. Faculty variables that did not vary over time (e.g., academic degree, sex, and department) were not included in these models, since they would be collinear with the faculty-member indicator variables. Moreover, in the conditional Poisson model, estimates were based only on observations in which the sum of the outcome variable was not zero — that is, data for faculty members who had at least one patent during their career.[9]

RESULTS

GROWTH OF PATENTING BY MEDICAL SCHOOL FACULTY

Figure 1 shows that the number of patents granted to faculty members from the AAMC Faculty Roster increased dramatically over time. The number of patents granted to medical school faculty increased from 122 in 1976 to 2175 in 2003 (with a peak of 2664 in 1999). This increase was not simply due to the increase in the number of medical school faculty during this period, since the increase was also evident on a per capita basis, as shown in Figure 1.

Moreover, Figure 2 shows that patents granted to faculty members of medical schools accounted for an increasing share of all academic patents (from 29% in 1976 to 53% in 2003), even though the share of all domestically assigned patents from universities increased during this period. Similarly, academic biomedical patents represented an in-

Table 1. Distribution of Patent Holders among Departments.

Department	Patent Holders (N=7874)	Faculty Members (N=158,266)	Patent Holders/ Faculty Members	Department Share of All Patent Holders	Department Share of All Faculty Members
	number			*percent*	
Basic					
Anatomy	158	2,948	5.36	2.01	1.86
Biochemistry	748	4,447	16.82	9.50	2.81
Microbiology	611	3,270	18.69	7.76	2.07
Other basic sciences	632	2,628	24.05	8.03	1.66
Pathology	587	8,393	6.99	7.45	5.30
Pharmacology	440	3,109	14.15	5.59	1.96
Physiology	227	3,268	6.95	2.88	2.06
Total	3403	28,063	12.13	43.22	17.73
Clinical					
Anesthesiology	145	8,508	1.70	1.84	5.38
Dermatology	89	1,121	7.94	1.13	0.71
Internal medicine	1845	42,901	4.30	23.43	27.11
Neurology	223	4,406	5.06	2.83	2.78
Obstetrics and gynecology	119	6,380	1.87	1.51	4.03
Ophthalmology	176	2,964	5.94	2.24	1.87
Orthopedics	116	2,595	4.47	1.47	1.64
Otolaryngology	55	1,600	3.44	0.70	1.01
Pediatrics	362	15,429	2.35	4.60	9.75
Physical medicine and rehabilitation	18	1,553	1.16	0.23	0.98
Psychiatry	154	13,716	1.12	1.96	8.67
Radiology	521	10,546	4.94	6.62	6.66
Surgery	569	13,389	4.25	7.23	8.46
Total	4392	125,108	3.51	55.78	79.05
Other					
Allied health science	5	482	1.04	0.06	0.30
Dentistry	13	223	5.83	0.17	0.14
Public health and preventive medicine	51	3,727	1.37	0.65	2.35
Miscellaneous	10	663	1.51	0.13	0.42
Total	79	5,095	1.55	1.00	3.22

creasing proportion of all domestically assigned biomedical patents awarded during this period, even though biomedical patents increased as a share of all domestically assigned patents during this period.

DISTRIBUTION OF PATENTING BY INSTITUTION AND DEPARTMENT

Table 1 shows the number of patent holders and the total number of faculty members by department among medical schools. During the period from 1981 through 2000, a total of 7874 of these persons (5%) applied for at least one patent that was subsequently granted. Although the total numbers shown in Table 1 are based on the number of patents granted per year, the data on patents issued per faculty member that are presented here and below are based on the application date, since the application date was closer to the time when the research was completed.

The propensity to apply for a patent varied strikingly among departments. Although much of the discussion about the effect of patents on medical schools concerns faculty members who are engaged in patient-oriented research, in our study, the share of faculty members from clinical departments who were patent holders was 3.5%, which was significantly lower than the 12.1% of faculty members from basic science departments who were patent holders. Although in absolute terms there were more patent holders from clinical departments, this was due to the larger size of these departments (especially internal medicine) relative to the size of basic science departments.

FACULTY CHARACTERISTICS AND PATENTING

Table 2 shows the distribution of faculty members who were granted patents during this period, according to whether or not they were NIH grantees, sex, and academic degree. Overall, almost 5% of faculty members were issued one or more patents that were applied for during the period from 1981 through 2000. Moreover, the propensity to apply for a patent was significantly higher among NIH grantees than among non-NIH grantees. The propensity to apply for a patent was also significantly higher for faculty members with Ph.D. or M.D.–Ph.D. degrees than for those with M.D. degrees. We determined the robustness of these correlations in multivariate regressions.

Table 3 shows the results of the multivariate Poisson regression models. The findings from our first model do not include the NIH funding variables. The estimated coefficients for experience suggest a curvilinear effect of experience on the probability of patenting with the probability peaking 12 years after a researcher earned his or her final academic degree and declining thereafter. These multivariate results also confirm the results shown in Table 2. Female faculty members were 63% less likely to be patent holders than their male counterparts (P<0.001). Moreover, the probability of being a patent holder was significantly higher for medical school faculty members with Ph.D. degrees or M.D.–Ph.D. degrees than for faculty members with M.D. degrees. When all other variables in the model were held constant at their mean values, faculty members with Ph.D. degrees and those with M.D.–Ph.D. degrees were almost three times as likely to be patent holders as faculty members with M.D. degrees (P<0.001). Finally, a person's propensity to apply for a patent was also positively associated with the cumulative number of patents applied for by other faculty members in the same department.

The results of the second model also include the variables for previous NIH funding. A faculty member's NIH funding in the previous year was positively associated with the propensity to apply for a patent. The effect was also significant (P<0.001). At the mean values of the other variables, an increase of 1 SD ($290,413) in NIH funding in the previous year was associated with a 2.08% increase in the probability of applying for a patent. NIH funding 2 years previously did not have a significant effect on the probability of applying for a patent, although the cumulative stock of lagged funding did have such an effect.

The third model includes indicator variables for each faculty member. The corresponding estimates are based solely on changes in the explanatory variables and patenting during a faculty member's career. After including individual effects, the influence of NIH funding in the first year remained positive and of the same magnitude as that in model 2, but the effects of funding in the second year and of cumulative funding up to the third year were no longer significant.

Table 2. Characteristics of Faculty Members.*

Variable	Non–Patent Holder (N=150,392)	Patent Holder (N=7874)
	number (percent)	
NIH grantee		
No	118,558 (98.46)	1860 (1.54)
Yes	31,834 (84.11)	6014 (15.89)
Sex		
Male	116,635 (94.31)	7039 (5.69)
Female	33,757 (97.59)	835 (2.41)
Degree		
M.D.	105,192 (97.40)	2804 (2.60)
Ph.D.	36,725 (90.01)	4074 (9.99)
M.D.–Ph.D.	8,475 (89.48)	996 (10.52)

* The denominator is the total number of faculty members for each variable. NIH denotes National Institutes of Health.

DISCUSSION

Our results clearly show an increase over time in the number of patents held by faculty members of medical schools during the period from 1981 through 2000. Although there is some evidence of a recent decline, it is unclear whether this decline is a deviation from the long-term trend. Overall, there has been an increase in the number of patents held by faculty members in academic medical centers during the past decades. This increase is of interest, given the historical reluctance by medical school faculty, and medical schools themselves, to be involved in these activities. At first glance, these results provide support for the notion that there has been a change in norms for patenting in U.S. medical schools.

However, we also found that patenting is concentrated among a relatively small number of departments and faculty members within medical schools. In particular, clinical faculty members were much less likely to be patent holders than their counterparts in basic science departments. In part, this difference reflects the fact that a substantial number of clinical faculty members are primarily engaged in clinical work and are therefore less "at risk" for patenting than faculty members in basic science departments.

We observed a strong positive relationship between recent scientific productivity, as measured by receipt of NIH funding, and involvement in patenting. This relationship may reflect the direct effect of NIH funds on the number of patents; in other words, faculty members with more resources generate more patents. Another interpretation

Table 3. Rate of Patenting According to Faculty Characteristics and NIH Funding.*

Variable	Model 1		Model 2		Model 3	
	Relative Rate (95% CI)	P Value	Relative Rate (95% CI)	P Value	Relative Rate (95% CI)	P Value
Sex						
Male†	1.00		1.00			
Female	0.37 (0.33–0.42)	<0.001	0.38 (0.33–0.42)	<0.001		
Experience						
Yr since last academic degree	1.09 (1.07–1.10)	<0.001	1.09 (1.07–1.10)	<0.001	1.36 (1.16–1.60)	<0.001
Yr squared	0.998 (0.998–0.999)	<0.001	0.998 (0.998–0.999)	<0.001	0.998 (0.997–0.998)	<0.001
Degree						
M.D.†	1.00		1.00			
Ph.D.	2.82 (2.52–3.17)	<0.001	2.69 (2.52–3.17)	<0.001		
M.D.– Ph.D.	2.99 (2.63–3.40)	<0.001	2.81 (2.63–3.40)	<0.001		
Cumulative no. of patents for faculty in the same department	1.002 (1.001–1.002)	<0.001	1.002 (1.001–1.002)	<0.001	0.999 (0.998–1.000)	0.31
NIH funding						
Previous yr			1.09 (1.06–1.12)	<0.001	1.13 (1.07–1.19)	<0.001
2 yr previously			1.02 (0.99–1.06)	0.24	1.05 (1.00–1.10)	0.05
Cumulative, up to 3 yr previously			1.03 (1.03–1.04)	<0.001	1.01 (1.00–1.03)	0.16
Faculty indicator variables‡	No		No		Yes	
No. of faculty	158,266		158,266		7,674	
No. of observations	1,471,377		1,471,377		114,046	

* Estimates of the relative rate were obtained from Poisson regression models (models 1 and 2) and from a conditional fixed-effects Poisson regression model (model 3). The confidence intervals are based on robust standard errors. In models 1 and 2, the confidence intervals incorporate clustering at the faculty level. In addition to the variables shown, all three models were adjusted for the calendar year indicator variables, and models 1 and 2 were adjusted for the department. The number of observations is smaller in model 3 because the estimates are based on variations within the faculty over time; faculty members who were never patent holders were excluded from the analysis. Estimates for sex and degree type are not reported in this model because these variables are fixed in time. NIH denotes National Institutes of Health, and CI confidence interval.

† The faculty members in these categories served as a reference group.

‡ Faculty indicator variables take on the value of 1 for all observations corresponding to a given faculty member and 0 for all other observations.

is that the results of new research — those likely to pave the road for future NIH grants — are also likely to result in patents. Our finding that patenting activity was most strongly related to NIH grants received in the previous year provides some support for the latter interpretation, since it is implausible that these recent grants were directly resulting in patents. However, we cannot make this conclusion definitively, since the values of the variables associated with lagged funding are likely to be similar, given a 3-to-5-year grant cycle for NIH grants.

We also found that patenting activity within academic departments was associated with the propensity of individual faculty members to seek patents. Previous literature suggests that academic institutions vary with regard to perceptions of whether patenting and technology transfer are consistent with their missions.[10] Our results suggest that views on patent holding differ among academic disciplines and, thus, among departments. However, they could also reflect labor-market sorting; that is, persons may be more likely to be attracted to (or attractive to) departments with faculty members who have similar patenting proclivities.

One potential limitation in interpreting our results is that different types of NIH grants may provide different signals of investigative vigor. Although all of the results described above are based on a specific set of individual-level grants, additional analyses showed that the results are robust with regard to the inclusion of center grants or to a definition of funding that is restricted to R01 grants (i.e., grants for research initiated by individual investigators).

In addition to the variables that we included, another potentially important factor affecting the propensity to apply for a patent at the individual or institutional level is industrial funding of biomedical research. Unfortunately, systematic data on this variable are unavailable.

Our data and analyses suggest that, increasingly, medical school research leads to patents, as well as to more traditional outcomes of scientific research. However, our results do not speak to the effects of increased patenting on the transfer or diffusion of patented knowledge. The consequences of these changes will depend on whether and how the patents affect the extent of university–industry technology transfer and the productivity of subsequent scientific research.[11] These are extremely important topics for future research.

Finally, although much attention has been focused on clinical researchers, our data show that the proportion of clinical faculty members who are patent holders is extremely small. Most clinical faculty members are not patent holders and are thus not subject to the conflicts of interest created by intellectual property rights. Other conflict-of-interest issues may be at play — for example, the relationships of faculty members with consulting firms and their equity holdings or reliance on industrial funding. Investigators who are involved in specific types of clinical research (e.g., drug or device trials) also may be more likely to apply for a patent and perhaps are more prone to conflicts of interest.

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