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Title

The enabling effect of interaction with clinical researchers in life sciences

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Current studies argue that biomedical research forms only one of three critical sources for medical advances (Nelson, Buterbaugh et al. 2011), highlighting clinical practice is another important source (Hamilton and Martin 2011). This difference in effects so has been argued on the basis of evidence single cases. To our knowledge the effect has not previously been demonstrated in systematic quantitative analysis, and therefore this paper seeks to illuminate the degree to which clinical research contributes to medical advances. Through utilization of patent data we identify how clinical researchers in the form of hospital researchers interact with university scientists in patenting, and how the scope of the patented invention determines the impact of the clinical researcher.

We ask two questions:

- Does the inclusion of a clinical researcher in the inventor group of a patent affect the value of the patent?
- When university and clinical researchers collaborate on a patentable invention, does the impact the clinical researcher have on patent value depend on the scope of the invention?

Our study is based on a bibliometric database covering three departments at University of Copenhagen from 1995 to 2005, using both publication and patent data. The departments chosen are the department of molecular biology (IMB), department of molecular pathology (IMP) and department of molecular biochemistry and genetics (IMBG). IMB is located in the faculty of life sciences and directed towards basic research within molecular biology, whereas IMP and IMBG are both located in the faculty of medicine, working on more clinically oriented research with a higher degree of collaboration with the University Hospital of Copenhagen. The selection of departments oriented towards both basic and clinical science allows for a more in-depth study of the different mechanisms affecting the interaction between university researchers and clinical researchers in hospitals and the life science industry, and encompass the majority of life science related research at the university. In addition to the publications from the period 1995-2005, we also collect publications made by the university scientists prior to 1995 in order to fully gauge the experience of the researchers and avoid any omitted bias caused by left censoring the data. The dataset covers 453 researchers with at least one publication, and a total of 2117 publications recorded in SCI journals, and 287 patents with at least one university researcher as an inventor appearing in Derwent Innovation Index.

With the use of publication data, an academic profile is created for each university researcher, covering collaboration patterns, academic quality measured in citations, scientific topics covered, and the quality and orientation of the journals published in. We pay particular attention to collaboration patterns, recording the composition of authors on all publications. This enables us to identify the degree to which a given university researcher have experience in collaborating with clinical researchers, or

exclusive works with other university researchers. The variables `Clinical_coauthors` and `University_coauthors` represent the ratio of clinical and university researchers in prior collaborations respectively. Note that this does not add up to 100% as CRO's, NGO's and industry researchers are also present in the dataset, albeit at low volumes. The variable `Clinical_coauthors` is utilized to identify whether a university researcher have any experience with clinical research and to what degree, assuming that continuous research collaboration with clinical researchers would increase the knowledge of the university researcher within clinical research topics.

This is combined with patent data where the university researcher appears as an inventor, using these patents as a proxy for the generation of a potential commercial innovation. We make use of patent forward citations (`Forward_citations`) to gauge patent value (Harhoff, Scherer et al. 2003), which is used as out dependent variable. We control for patent family size, technological scope (measured in number of IPC classes of the patent), designated states, and the age of the patent. We also include controls for ownership of patents using the number of assignees from universities, hospitals, firms and individuals respectively. Particularly industry ownership can be an indicator of value as firms rarely seek patent ownership without the patent having a strategic value to the firm.

In order to identify how the technological scope of the patent affects the impact of including a clinical researcher in the inventor group, we attempt to identify the patents that are related to the development of medical technology, as opposed to pure drug development. To achieve this we make use of the international patent classification (IPC), where two main classes can be used. Patents classified only within the C class (chemistry, including biochemistry) are classified as drug discovery patents (`Drug_development`), whereas patents including the A class (human necessities, which medical technology such as medical devices cover) are used to identify an invention including an element of medical technology (`Medical_technology`). While this method is a rough estimate, it does provide an insight into the technological scope of the patent, and allows for the use of interactions in our regression models that can highlight to which technological domains clinical researchers contribute the most. We are currently consulting with technical experts within life sciences in order to develop a more accurate classification of life science patents. We employ a negative binomial regression using robust standard errors. A Vuong test was used to test for the validity of a zero inflated model(Wooldridge 2009).

We find that while the presence of a clinical researcher in the inventor group does not affect overall patent value, it has a very different impact depending on the technological scope of the patent. We find that clinical researchers have a positive significant effect on the value of patents within medical technology, indicating that experience with clinical research and clinical application are best brought to bear on

the development of medical technologies rather than drug discovery, which show a negative significant effect.

Tables

Table 1 – Descriptive statistics

Variable	Obs	Mean	Std. Dev.	Min	Max
Forward_citations	287	3.082988	9.868861	0	39
IPC_count	287	8.958506	6.091376	3	52
Family_size	287	3.008299	2.776376	2	13
Designated_states	287	24.49253	15.50363	4	37
Patent_age	287	13.02988	17.09075	0	23
Medical_technology	287	.3655602	.4231938	0	1
Drug_development	287	.4788382	.4622963	0	1
Hosp_inventor	287	.0905436	.163656	0	1
Assignee_hospital	287	.9788382	1.362963	0	3
Assignee_firm	287	3.095436	1.563656	0	7
Assignee_individual	287	2.59751	2.194651	0	9
Assignee_count	287	3.37706	.6248577	1	4
Inventor_count	287	2.006519	1.796588	1	6
Tenured	287	.4348166	.2447978	0	1
Gender	287	.2104701	.4078605	0	1
Years_employed	287	8.202991	7.236674	4	25
Total_publications	287	28.43782	52.55726	12	207
Total_citations	287	488.8614	1078.014	5	6437
Avg_impact_factor	287	4.506519	1.796588	2.273222	13.12431
Clinical_coauthors	287	.0082988	.0909075	0	1
University_coauthors	287	.4484936	.3275633	0	1
Medical_school	287	.4979253	.5010363	0	1

Table 2 - Forward_citations – Negative binomial regression using robust standard errors

	Model 1	Model 2	Model 3
Patent characteristics			
IPC_count	0.048	0.048	0.048
	[0.037]	[0.037]	[0.037]
Family_size	0.012**	0.011**	0.012**
	[0.003]	[0.003]	[0.004]
Designated_states	0.027	0.027	0.027
	[0.053]	[0.053]	[0.053]
Patent_age	0.645	0.643	0.638
	[0.585]	[0.579]	[0.590]
Medical_technol.		0.090	
		[0.052]	
Drug_development			0.163
			[0.118]
Hosp_inventor	0.082	0.090	0.085
	[0.056]	[0.052]	[0.067]
*Medical_technol.		0.012***	
		[0.004]	
*Drug_development			-0.128***
			[0.037]
Assignee_hospital	-0.705	-0.705	-0.704
	[0.497]	[0.498]	[0.497]
Assignee_firm	0.151*	0.151*	0.151*
	[0.081]	[0.081]	[0.081]
*Medical_technol.		0.076	
		[0.101]	
*Drug_development			0.040**
			[0.021]
Assignee_individual	0.111	0.112	0.111
	[0.071]	[0.075]	[0.072]
Assignee_count	0.252**	0.249**	0.251**
	[0.090]	[0.088]	[0.091]
Inventor_count	0.101*	0.102*	0.099*
	[0.057]	[0.058]	[0.053]
University inventor characteristics			
Tenured	-0.077	-0.076	-0.076
	[0.261]	[0.259]	[0.261]
Gender	0.276	0.281	0.275
	[0.224]	[0.212]	[0.222]
Years_employed	-0.057	-0.057	-0.056
	[0.125]	[0.124]	[0.125]
Total_publications	0.175*	0.175*	0.175*
	[0.104]	[0.103]	[0.104]
Total_cites	0.162*	0.162*	0.162*
	[0.100]	[0.101]	[0.099]
Avg_impact_factor	0.107	0.107	0.107
	[0.129]	[0.129]	[0.129]
Clinical_coauthors	0.249*	0.550**	0.552**
	[0.105]	[0.225]	[0.219]
University_coauth.	-0.128	-0.128	-0.128
	[0.277]	[0.277]	[0.277]
Medical_school	-0.085***	-0.085***	-0.085***
	[0.056]	[0.056]	[0.056]
Constant	-0.364**	-0.364**	-0.323**
	[0.171]	[0.170]	[0.138]
No of Obs	287	287	287
Log likelyhood	-394.1609	-401.1407	-386.2409
Pseudo R-squ~d	.05037	.05023	.04851
F test			

* p<0.1, ** p<0.05, *** p<0.01

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> We combine estimates of the value of patent rights from a survey of patent-holders with a set of indicator variables in order to model the value of patents. Our results suggest that the number of references to the patent literature as well as the citations a patent receives are positively related to its value. References to the non-patent literature are informative about the value of pharmaceutical and chemical patents, but not in other technical fields. Patents which are upheld in opposition and annulment procedures and patents representing large international patent families are particularly valuable. (C) 2002 Elsevier Science B.V. All rights reserved.

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