Predicting commercial success for Australian medical inventions patented in the United States: a cross sectional survey of Australian inventors

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ABSTRACT

Objectives: To examine the commercial development of Australian medical patents and identify the determinants of their being used in innovations (new or improved products or production processes).

Design: Cross-sectional survey with a nested case–control study.

Participants and setting: 177 inventors listed as the first Australian on medical patents granted in the United States between 1 January 1984 and 30 December 1994, and surveyed in 1998–1999.

Main outcome measure: A series of predictor variables (including characteristics of the patents; characteristics of the inventors; ideas, advice and funding during commercialisation; and the process of commercialisation) for whether or not a patent became an innovation.

Results: Half (89/177) of the medical patents became innovations, with 34% generating a total of A $287 million (13% over $1 million) in annual sales a median of 8 years after the patent had been granted. A patent was more likely to become an innovation if the inventor was employed by industry at the time of invention (odds ratio [OR], 3.2; 95% CI, 1.1–9.2), had invested their own finances (OR, 2.8; 95% CI, 1.0–7.4), and if the patent had been licensed (OR, 4.6; 95% CI 1.7–12.7), led to further patents (OR, 3.2; 95% CI, 1.0–10.4) and involved an industry partner in its commercial development (OR, 10.1; 95% CI, 3.6–27.7). It was less likely to become an innovation if finance came from a research funding agency (OR, 0.3; 95% CI, 0.1–0.8) and if interest from Australian industry was judged by inventors as "poor" (OR, 0.6; 95% CI, 0.4–0.9).

Conclusions: Medical patents in the US listing Australian inventors are more likely to become innovations if they originate from industry rather than the public sector, and if inventors are willing to invest their own finances.

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Medical patents — defined here as patents for any technology for managing patients and their illnesses, preventing illness, or for medical research — account for an increasing proportion of Australia's intellectual property portfolio,[1] and there is increasing interest in harnessing the commercial potential of Australian medical research.[2] The purpose of our study was to identify the commercial outcomes of Australian medical patents and to isolate which factors predict a successful outcome.

Medical industries are among the most profitable worldwide[3] and use patents extensively to protect their inventions.[4-6] Despite this, no study has explored the commercialisation process from medical patent to technological innovation using a national or "whole-of-population" approach. A patent is only classified as a technological innovation once it becomes embodied in a new or improved product or production process.[7] Such innovations are considered the main contributors to economic growth.[8,9]

The medical market in the United States is the largest in the world, and the US is therefore the first foreign country where multinational corporations submit their patent applications.[10] Medical patents account for a growing proportion of all US patents granted to Australian inventors, increasing from 10% in 1984 to 25% in 1999.[1] Thus, examining medical patents in the US is an efficient means of assessing the commercial potential of Ausralian medical patents.

We describe a survey of Australian inventors listed on medical patents granted in the US from 1984 to 1994. Our main aim was to identify the determinants of innovation by comparing patents that became innovations with those that did not.

METHODS

There were 4707 utility patents listing Australian inventors in the US between 1 January 1984 and 30 December 1994. Of these, 602 (13%) were categorised as being medical in our previous study,[1] and 402 inventors were the first Australians listed on one or more of these patents. This study is a cross-sectional survey, taking a whole-of-population approach by involving all 402 first-named Australian inventors identified on these medical patents.

We conducted a postal and follow-up phone survey in 1998 and 1999 of all inventors for whom an address was found through a variety of sources.[11-14] The inventors were asked to answer questions about their earliest listed patent in the US during our study period which had not expired.

Patents only become innovations if the technology has been introduced on the market or used within a production process.[7] Thus, an innovation was any patent which led to a product or production process which generated sales.

Statistical analysis

Statistical analysis was conducted with SPSS for Windows (version 10.1; SPSS Inc, Chicago, Ill, USA). Logistic regression analysis[15]

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was used to identify the most important determinants for patents to become innovations. To avoid confounding by the commercialisation process itself, this analysis focused on variables representing early stages of commercialisation.

Ethical approval

This study was approved by the Committee for Human Rights of the University of Western Australia.

RESULTS

Sample characteristics

Of the 402 first-named Australian inventors identified on the US medical patents, possible addresses were found for 350 inventors. Among the 350 mail-out questionnaires sent to these inventors, 76 were returned to sender, suggesting that these addresses were incorrect. Thus, 274 correct addresses were found and 177 inventors responded to the mail-out (137) and phone (40) surveys, giving a response rate of 65%.

We undertook two comparisons to check for response bias. First, there was no statistically detectable bias when comparing the nine characteristics of patents between the 177 inventors who were surveyed (respondents) and the 225 who were not part of the survey (non-respondents). (Data available from authors.) Second, of the 177 surveyed inventors, the 137 mail-out respondents, were put side by side with the random sample of 40 who agreed to be surveyed after being contacted by phone (a random sample of non-respondents to the mail-out survey). Not only was there no significant difference in patent characteristics, but for both groups, half of the patents became technological innovations (53% for mail-out respondents and 47% for phone respondents; $\chi^2 = 0.324$; $P = 0.569$; data available from the authors.)

Only 3% (6/177) of the surveyed Australian medical inventors were female. Inventors had undergraduate training in science (44%), medicine (25%) or engineering (15%). Half (53%) had completed a doctorate, 10% a masters degree, 8% a postgraduate diploma and 15% a bachelors degree. A quarter (46/177) of medical inventors had patient care responsibilities, mainly as physicians (10%) and surgeons (8%).

1 Determinants of innovation — characteristics of medical patents

	Innovation	Non-innovation	*P*
No. of patents*	89	84	
Inventors			
Patents listing two or more inventors	43 (48%)	49 (58%)	0.187‡
Patents listing non-Australian inventors	7 (8%)	12 (14%)	0.177‡
Assignees			
Patents listing one or more assignees	61 (69%)	63 (75%)	0.346‡
Assigning of patents†			0.637‡§
Unassigned	28 (32%)	21 (25%)	
Australian assignees	47 (53%)	48 (57%)	
Non-Australian ±Australian assignees	14 (16%)	15 (18%)	
Categorising first assignee of patents			0.333‡§
Unassigned	28 (32%)	21 (25%)	
Business	39 (44%)	27 (32%)	
University	10 (11%)	15 (18%)	
Government	4 (4%)	6 (7%)	
Research institute	2 (2%)	5 (6%)	
CSIRO	3 (3%)	4 (5%)	
Remaining categories	3 (3%)	6 (7%)	
Citations			
Patents listing one or more citations	42 (47%)	50 (60%)	0.104‡
Technology			
Biotechnology patents	13 (15%)	19 (23%)	0.175‡
Clinical application of patented technology			0.205‡§
Therapeutic device	28 (32%)	16 (19%)	
Drug	13 (15%)	20 (24%)	
Implantable device	15 (17%)	11 (13%)	
Diagnostic device	10 (11%)	12 (14%)	
Diagnostic test	11 (12%)	6 (7%)	
Biotechnology method/device	3 (3%)	5 (6%)	
Other applications	9 (10%)	14 (17%)	

* Four patents were excluded because the commercial outcome was not known by the surveyed inventors. † Unassigned patents are owned by the inventor(s) listed on the patent and do not list an assignee (or owner), whereas assigned patents list inventor(s) and assignee(s). ‡ Pearson χ^2. § Overall χ^2.
CSIRO = Commonwealth Scientific and Industrial Research Organisation. ◆

Source of inventions

The main source of invention is taken as the workplace of the inventor at the time of coming up with the patented invention. Thus, most medical patents in the US listing Australian medical inventors come from government-funded organisations (53%). These include universities (30%), public hospitals (10%), the Commonwealth Scientific and Industrial Research Organisation (CSIRO; 7%), the Australian Government (3%), and public research institutions (2%). Conversely, 41% (73/177) of inventors came from the private sector, including industry (27%), private clinical practice (8%), private research institutions (4%) and the self-employed (3%). The remaining 6% came from inventors with multiple areas of employment (4%), and those who were unemployed (1%), retired (0.6%) or working for a non-government organisation (0.6%).

Commercialisation

The median cost to commercialise a medical patent was between A$100 000 and A$500 000 (148 respondents). Three quarters (135/177) of patents involved an industry partner at some stage during the development process. Barely 3% (6/177) of patented technology led to the creation of a start-up company. Fifty-eight per cent (102/177) of patented medical technology ended up being manufactured, and 53% gave a duration of manufacture; 32% of patented technology was manufactured or used in a production process for more than 4 years, 14% for 1–4 years and 7% for less than 1 year — a median duration of more than 4 years. Of all patented technology:

2 Determinants of innovation — characteristics of inventors

	Innovation	Non-innovation	*P*
No. of patents*	89	84	
Male:female ratio (%female)	84:5 (6%)	83:1 (1%)	0.112‡
Inventor's area of employment at time of developing intellectual property†			0.008‡§
University	25 (28%)	29 (34%)	0.361‡
Industry	32 (36%)	15 (18%)	0.007‡
Hospital	12 (14%)	6 (7%)	0.172‡
Private clinical practice	8 (9%)	6 (7%)	0.656‡
CSIRO	5 (6%)	7 (8%)	0.482‡
Research institute	1 (1%)	9 (11%)	0.007‡
Other	6 (7%)	12 (14%)	0.104‡
Highest educational qualification			0.027¶
Doctorate	39 (44%)	53 (63%)	0.011‡
Masters degree	11 (12%)	6 (7%)	0.249‡
Postgraduate diploma	9 (10%)	5 (6%)	0.316‡
Bachelors degree	14 (16%)	11 (13%)	0.622‡
Graduate diploma	3 (3%)	4 (5%)	0.643‡
No tertiary qualification	13 (15%)	5 (6%)	0.062‡
Background			0.387‡§
Science	37 (42%)	41 (49%)	
Medicine	21 (24%)	22 (26%)	
Engineering	13 (15%)	13 (16%)	
Other tertiary qualification	5 (6%)	3 (4%)	
No tertiary qualification	13 (15%)	5 (6%)	
Patient care responsibilities	23 (26%)	21 (25%)	0.899‡
Previous involvement with business related to patent	28 (32%)	21 (25%)	0.346‡
Authored one or more provisional patents	54 (61%)	36 (43%)	0.019‡
Authored one or more granted patents	63 (71%)	47 (56%)	0.043‡

* Four patents were excluded because the commercial outcome was not known by the surveyed inventors.
† Taken as the source of invention. ‡ Pearson χ^2. § Overall χ^2. ¶ Linear-by-linear association (ie, χ^2 test for trend).
CSIRO = Commonwealth Scientific and Industrial Research Organisation. ◆

- 34% generated a total of $287 million in sales in the financial year before the survey (a median of 8 years after patents had been granted); and
- 13% produced annual sales of over $1 million.

Assuming a median duration of manufacture of 5 years, the average sales generated per patent were $8.1 million.

The final commercial outcome of the survey was that 50% of patents resulted in a technological innovation.

As a proportion of all 177 patents, innovations ended up being manufactured in Australia (33%), the US (16%), the United Kingdom (5%), Germany (4%) and Japan (3%), with 13% (23/177) being manufactured in two or more countries, including 8% in Australia and the US.

Predictors of innovative potential

No single characteristic of patents themselves that we considered predicted innovative potential (Box 1). However, the survey showed that the inventor's area of employment at the time of invention is a very strong predictor of commercial success (Box 2). Inventors who worked for industry had commercialised two-thirds of their patents (32/47; 68%), and those who worked for a university, a hospital, the CSIRO, or were in private clinical practice had commercialised around half their patents; among those who worked for a research institute, only 10% of patents (1/10) became innovations.

Interestingly, there was no difference between inventors whose patents became innovations and those whose patents did not in terms of their background, previous business experience, or whether or not they had clinical responsibilities (Box 2). However, inventors who had a doctorate were less likely to be successful, probably reflecting the source of these patents, with 76% (70/92) working for a university, a research institute, a hospital or the CSIRO at the time of invention. On the other hand, inventors who had authored one or more provisional and granted patents were more likely to generate an innovation.

The source of ideas and information did not influence whether or not a patent became an innovation (Box 3). Seeking advice on commercialisation from a patent attorney or others did not predict success. However, patents arising from research with financial support from a research funding agency were less likely to become innovations.

Strong predictors of success were use of the inventor's own finances in the development process, and if an Australian research and development tax concession or a grant from a government commercialisation program was obtained.

As anticipated, the cost of commercialising successful patents tended to be higher than for unsuccessful ones.

Patented technology which led to a licence or to an international extension of protection or to further patents was more likely to encounter commercial success (Box 4). Not surprisingly, a good marker for developing an innovation was the current involvement of an industry partner.

During the development of patents, 75% had a prototype made or tested, 64% involved market research and a third included a business plan. However, against expectations these activities did not increase the likelihood of generating an innovation (Box 4).

Successful inventors were less likely to complain about "poor" interest from industry in Australia than unsuccessful inventors (Box 4). They also appeared to have a better understanding of domestic and international markets, to trust their industry partner and to generate products with high acceptance and demand among customers.

Multivariable analysis of determinants found to be significant in the bivariate analysis and considered to be implicated early in the commercialisation process (Box 5) found a greater likelihood of a medical patent becoming an innovation if:

- the inventor was employed by industry at the time of invention;

3 Ideas, advice and funding during commercialisation as determinants of innovation

	Innovation	Non-innovation	*P*
No. of patents*	89	84	
Sources of ideas and information†			
Research and development in your workplace	55 (62%)	61 (73%)	0.130‡‡
Industry research and development outside your work	17 (19%)	8 (10%)	0.073‡‡
From treating patients	27 (30%)	15 (18%)	0.056‡‡
Universities	15 (17%)	19 (23%)	0.340‡‡
Professional journals	27 (30%)	24 (29%)	0.799‡‡
Patent attorney used as an advisor during commercialisation	50 (56%)	45 (54%)	0.730‡‡
Used one or more advisors during commercialisation	80 (90%)	67 (80%)	0.063‡‡
No. of patents*	84	80	
Funding from any registered research funding agency‡	17 (20%)	28 (35%)	0.034‡‡
No. of patents*	86	74	
Source of finance†			
Personal	36 (42%)	19 (26%)	0.032‡‡
Organisation where invention arose	15 (17%)	20 (27%)	0.144‡‡
Employer	18 (21%)	22 (30%)	0.200‡‡
Industry partner	28 (33%)	24 (32%)	0.986‡‡
Australian research and development tax concession	18 (21%)	2 (3%)	0.001‡‡
No. of patents*	81	69	
Government commercialisation program used during development§	29 (36%)	2 (3%)	< 0.001‡‡
No. of patents*	80	67	
Cost of commercialisation¶			0.004§§
< $10 000	3 (4%)	8 (12%)	
$10 000 to < 50 000	15 (19%)	21 (31%)	
$50 000 to < 100 000	7 (9%)	6 (9%)††	
$100 000 to < 500 000	21 (26%)**	16 (24%)	
$500 000 to < 1 million	12 (15%)	6 (9%)	
$1 million to < 10 million	16 (20%)	7 (10%)	
$10 million to < 50 million	5 (6%)	2 (3%)	
$50 million to 99 million	1 (1%)	1 (2%)	

* Includes patents for which respondents provided an answer to the relevant question. † Subcategories are not mutually exclusive (hence an overall χ^2 analysis could not be performed). ‡ Predominantly includes funding from the National Health and Medical Research Council (9 innovations [11%] and 16 non-innovations [20%]; $\chi^2 = 2.791$; $P = 0.095$). § Includes Export Market Development Grants Scheme, National Industry Extension Service World Class Manufacturing and Export Finance Insurance Corporation. ¶ Costs relate inventors' response to the question "What has it cost to commercialise your invention to date?". ** Median category for the innovation group. †† Median category for the non-innovation group. ‡‡ Pearson χ^2. §§ Linear-by-linear association (ie, χ^2 test for trend). ◆

- the patent had been licensed;
- the patent had been modified leading to further patents;
- the inventor had invested their personal finances; and
- an industry partner was currently involved.

In contrast, a patent was less likely to become an innovation if the research leading to the patent was funded by a research funding agency or if the inventor deemed that interest from industry in Australia was "poor".

DISCUSSION

Our study shows that US medical patents granted to Australian inventors in 1984–1994 have an enormous commercial potential, with 50% becoming technological innovations. This is in keeping with previous surveys of inventors which found that between 30% and 55% became innovations.[16-20]

The median duration of manufacture of patented technology is more than 4 years for patents which are commercialised, which is consistent with previous findings that the median duration was 5–9 years.[17]

Very few women are medical inventors (3%), consistent with previous work which found that women accounted for 0.4%–3.5% of inventors listed on patents.[16,17,21-23] This may change with the increasing participation of women in science, medicine and engineering.

If patent characteristics available on the patent databases could be used to assess the relative commercial value of a patent, that would be very useful to, for example, venture capitalists. Disappointingly, none of the characteristics we examined were predictive of innovation potential.

We found that source of invention is a strong predictor of success, with inventions arising from industry being the most successful (two-thirds became innovations), while half of those from the public sector, especially universities, became innovations. This may be why patents which originated from research supported by research funding agencies are less successful.

A patent being licensed was predictive of it becoming an innovation. This reflects the high proportion of Australian medical patents (53%) arising from publicly-funded organisations, necessitating a vehicle for transferring the technology to industry. A patent would only lead to further patents if there was ongoing development and belief in its potential, and hence, this is a good indicator of commercial success.

Inventors investing their own money in the development of their patent made these patents three times as likely to end up as technological innovations. This suggests that inventors have a good appreciation of the commercial potential of their patents. In addition, if inventors found that interest in their patents from industry in Australia was "poor", these patents were unlikely to become innovations. This implies that lack of interest from the domestic industry is a good predictor of failure.

This is the first study to our knowledge that has examined the determinants of innovation for medical patents by means of a whole-of-population approach. Comparing characteristics of patents suggests there

4 Process of commercialisation as a determinant of innovation

	Innovation	Non-innovation	*P**
No. of patents†	89	84	
Patent outcome‡			
Sold	15 (17%)	8 (10%)	0.156
Licensed	44 (50%)	15 (18%)	< 0.001
Modified leading to further patents	23 (26%)	6 (7%)	0.001
Submitted in countries other than Australia and the United States	45 (51%)	28 (33%)	0.022
What happened to invention‡			
Business plan drafted	30 (34%)	28 (33%)	0.958
Market research undertaken	67 (75%)	54 (64%)	0.115
Prototype made or tested or in trial	71 (80%)	58 (69%)	0.105
Current industry partner involvement	77 (87%)	31 (37%)	< 0.001
Opinion of inventor‡			
Interest from industry in Australia is "poor"	33 (37%)	44 (52%)	0.043
Access to markets overseas is "poor"	31 (35%)	17 (20%)	0.032
Size of Australian market is "poor"	49 (55%)	27 (32%)	0.002
Trust of industry partner is "good"	39 (44%)	18 (21%)	0.002
Acceptance by customers or patients is "good"	65 (73%)	24 (29%)	< 0.001
Demand from customers is "good"	54 (61%)	15 (18%)	< 0.001

* Pearson χ^2. † Four patents were excluded because the commercial outcome was not known by the surveyed inventors. ‡ Subcategories are not mutually exclusive. ◆

5 Determinants found early in the commercialisation of 153 medical patents* that best predict generating an innovation

	Innovations	Non-innovations	Multivariable odds ratio (95% CI; *P*)
Inventor employed by industry at time of developing intellectual property			
No	51 (62%)	60 (85%)	1.00
Yes	31 (38%)	11 (15%)	3.22 (1.13–9.21; 0.029)
Patent was licensed			
No	42 (51%)	57 (80%)	1.00
Yes	40 (49%)	14 (20%)	4.64 (1.69–12.71; 0.003)
Patent was modified leading to further patents			
No	60 (73%)	65 (92%)	1.00
Yes	22 (27%)	6 (8%)	3.25 (1.02–10.40; 0.047)
Inventor provided personal finance for commercialising patent			
No	48 (58%)	52 (73%)	1.00
Yes	34 (42%)	19 (27%)	2.75 (1.02–7.39; 0.046)
Current involvement of an industry partner			
No	10 (12%)	43 (61%)	1.00
Yes	72 (88%)	28 (39%)	10.06 (3.65–27.68; < 0.001)
Research funding received from any registered research funding agency			
No	66 (80%)	46 (65%)	1.00
Yes	16 (20%)	25 (35%)	0.26 (0.09–0.77; 0.015)
Interest from industry in Australia is "poor"			
No	53 (65%)	27 (38%)	1.00
Yes	29 (35%)	44 (62%)	0.60 (0.38–0.95; 0.030)

* Survey respondents with missing values were excluded. ◆

was not a major response bias in the survey. The final list of determinants probably mirrored some unique features of commercialising Australian medical patents, especially the high proportion arising from publicly funded organisations. Determinants may also have changed with the evolution of the commercialisation environment in Australia, especially given the recent implementation of funds such as National Health and Medical Research Council Development Grants, Biotechnology Innovation Fund grants, Commercialising Emerging Technologies grants and Pre-Seed venture capital funding. The small sample size may mean some determinants of innovation were missed.

The only other study examining the determinants of innovation for patents was by Dagenais and colleagues.[24] They found that greater success was associated with inventors being under the age of 60, with an income of over Can$30 000 (A$31 116), who had used a patent attorney, were less educated, had authored more granted patents, and were not employed by a university or research institute. Our survey concurs with the last three findings. We did not look at the age or income of inventors. Any remaining differences may arise because the earlier study focused on individual inventors on unassigned patents.

Medical inventors are highly trained professionals who appear to be dependent on extensive university education, emphasising its importance in underpinning medical inventions and the value of tracking the number of university graduates.[25]

The most surprising finding is the crucial role that the Australian Government plays in all facets leading to innovation. Publicly-funded universities make up 38 of the 40 universities in Australia, and hence, provided the education of most Australian medical inventors. Not only did the government fund the education of medical inventors, a quarter of the research leading to a medical patent and half the organisations generating inventions, but it also contributed funding to the diffusion of 30% of patents, mainly through government grants and the research and development tax concessions.

New start-up companies are thought to be a crucial facet of technology transfer from universities and other public sector institutions, and a vital aspect of industry growth.[26] Hence, the low number of start-up companies resulting from Australian patents in the US could be considered a concern. Recent figures are more promising, indicating that Australia was ranked around

7th or 8th internationally for a number of measures of entrepreneurial activity.[27]

To estimate the impact of recent policy changes would necessitate, among other studies, a repetition of ours for patents granted in more recent years. We examined commercial success of medical patents in terms of innovation and sales. The next issues are to assess their profitability and, ultimately, their impact on population health. Further, although this hypothesis-generating study was able to identify possible determinants of innovation, establishing causality requires prospective cohort studies undertaken, preferably, in different countries. Finally, the commercialisation of medical patents is but a small tile in the mosaic of Australian innovation, thus determinants of innovation need to be sought broadly in our society.[28,29]

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COMPETING INTERESTS

None identified.

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