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Patent holdings of US biotherapeutic companies in major markets[☆]

Teena E. Sebastian, Chandra Bindu Yerram and Gayatri Saberwal, gayatri@ibab.ac.in

In previous studies we examined the (United States, US) patent holdings of 109 largely North American biotech companies developing therapeutics that, in particular, have an interest in discovery stage science. There appears little correlation between the number of patents and the number of products of individual companies. Here we quantified and compared the 103 US-headquartered companies' patent holdings in Australia, Canada, Europe, Japan and the US. The companies demonstrate variable and surprising patterns of patent holdings across these countries or regions. For most companies, patent holdings are not in proportion to the importance of the country as a biotech or pharma market. These results have implications for the patenting strategies of small biotech companies involved in drug discovery.

So far, most original drug discovery has taken place in the United States (US) and Europe. There is an impression that companies wishing to pursue this path need huge amounts of money and large numbers of patents; however, there are conflicting opinions related to this (see <http://www.citizen.org/publications/release.cf-m?ID=7065> and [1]). As drug development efforts pick up in countries such as India and China, it becomes important to map the requirements more precisely. We have, in two previous studies, quantified the US patent holdings of 109 (primarily) North American companies. Here we examine the patent holdings of 103 US-based biotherapeutic companies in various international markets.

Definition of the dataset

In previous studies, sample sets of 59 [1] and 50 (S. Yadav *et al.*, unpublished) were created of biotech companies with a focus on developing biotherapeutics. Of the 109 companies, 6 companies were headquartered outside the US, either in Canada (4) or the United Kingdom (2). These 6 companies (Aeterna Zentaris, Amarin, Hemosol, Oncolytics Biotech, QLT and Vernalis) were deleted, leaving a new dataset of 103 biotherapeutic companies with discovery science programmes that are headquartered in the US. Of these, a set of 58 companies comprises those that were formed in, or after, 1992 and are referred to as the new companies. 45 companies were formed between 1980 and 1991 inclusive and are referred to as the old companies.

Determination of patents for each company

We wanted to compare how many patents each company had in the US with their hold-

ings in a few other pharma markets, that is, Australia, Canada, Europe and Japan (for reasons of economy, we occasionally refer to Europe as a country). We looked up each company at the respective national online patent database or another authoritative source. As in our earlier studies, we also looked up the previous names (if any) of each company and added the patents in the old name(s) to the respective company's total. Although we had already examined the US patent holdings of these companies in our earlier work, we re-collated data from the US Patent and Trademark Office (USPTO) in the same time period that we were collecting that on the other countries to have updated and, therefore, more comparable data.

The USPTO was accessed at <http://patft.uspto.gov/netahtml/PTO/search-bool.html>, where the name of each company was searched as 'Assignee name'. The Canadian Patent Office database was searched at

[☆]For 103 US-headquartered biotherapeutic companies, we have quantified the patent holdings in major markets. The companies demonstrate variable and surprising patterns of these holdings.

<http://patents.ic.gc.ca/cipo/cpd/en/search/advanced.html>, where the company name was searched as 'Owner'. A point to note for the Canadian patent database is that both issued patents and filed applications are combined and only after checking each entry can the two be distinguished. Japanese patents were looked up at the Industrial Property Digital Library of the Japanese Patent Office (see <http://www19.ipdl.inpit.go.jp/PA1/cgi-bin/PA11-NIT?1212128133130>). We looked up the European and Australian patents at CAMBIA's Patent Lens (see <http://www.patentlens.net/patentlens/structured.cgi?Search#list>). To confirm that the database of Patent Lens is up to date, we compared a sample of the numbers of granted US patents at the Patent Lens website with that at the USPTO website. The numbers were identical except for occasional minor differences. This gives confidence that although Patent Lens is not a government website, it is a valid resource to examine the companies' Australian, European and US patent holdings.

Certain other aspects of our methodology were as follows. First, with regard to European patents, we wish to point out that a patent is counted only once, even though it may have been granted in several European countries. Second, although company names are sometimes misspelled in the patent databases, we have not investigated any variation of company names, having checked only the correct name at each patent database. Although we have undoubtedly missed a few patents, one presumes this error is randomly distributed across all companies and, therefore, does not affect the conclusions of the study. Finally, all data were collected in July 2008.

Findings

The old companies have a total of 5405 patents, of which 3622 (67%) are issued in the US, 674 (12%) in Australia, 309 (6%) in Canada, 758 (14%) in Europe and 42 (1%) in Japan (Supplementary Table 1 and Fig. 1). The new companies have a total of 3133 patents, of which 2228 (71%) are issued in the US, 532 (17%) in Australia, 68 (2%) in Canada, 297 (9%) in Europe and 8 (0%) in Japan (Supplementary Table 2 and Fig. 1).

We find that the companies may have small (0 or single digit) or large (double or triple digit) numbers of patents in a given country. There are various patterns of patent holdings across countries (Supplementary Tables 1 and 2, Fig. 2). In the 45 old companies, we

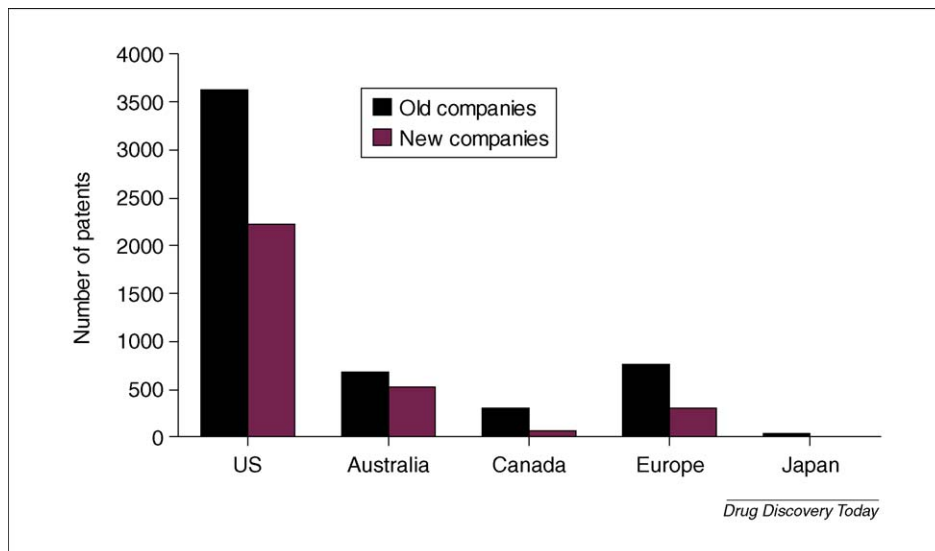


FIGURE 1

The number of patents held by old and new companies in specific countries (or regions).

identified 6 groups. (A) The first group contains a large number of patents in the US and also in one other country. This group holds 8 (18%) of the 45 companies. (B) There are some companies which have very few patents in Japan, but large holdings in all the other countries. This holds true for 9 (20%) of the companies. (C) Another pattern is of companies that have a low number of patents in Japan and Canada, but a large number in Australia, Europe and the US. This forms a group of 6 (13%) companies. (D) The largest group is of 16 com-

panies (36%) that have large holdings in the US, but low holdings in each of the other countries. (E) Then there is another small group of 5 (11%) companies with a small number of patents in all 5 countries. (F) The last group – that of unusual companies – comprises 1 (2%) company with a large number of patents in all countries. When we did a similar analysis of the 58 new companies, we found that with the exception of Group B, the same groups could be identified. The numbers and percentages

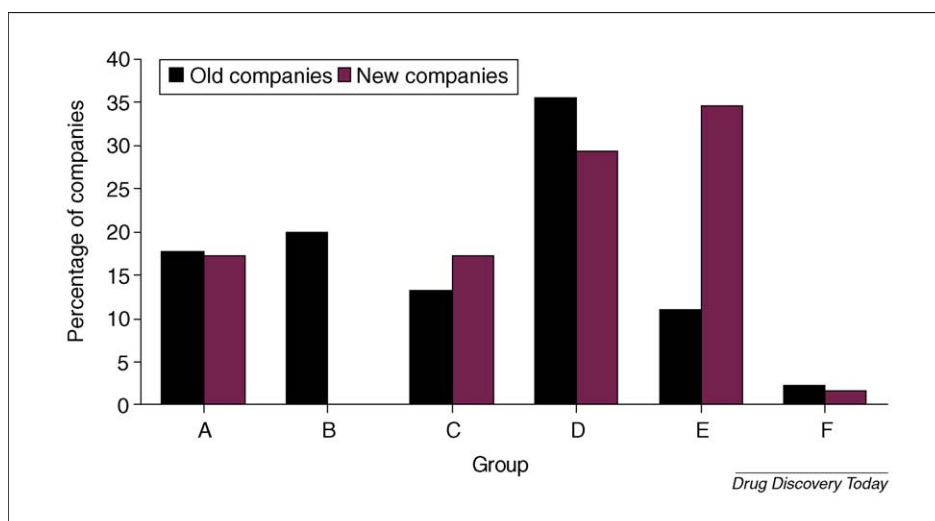


FIGURE 2

The percentage of old and new companies with different patterns of patent holdings. (A) A large number of patents in the US and in another country. (B) A small number of patents in Japan, but a large number in all other countries. (C) A small number of patents in Canada and Japan, but a large number in all other countries. (D) A large number of patents in the US and a small number in all other countries. (E) A small number of patents in all countries. (F) Unusual patent holdings.

for the groups are as follows: Group A and Group C have 10 (17%) companies each; Group D has 17 (29%); Group E has 20 (34%) and Group F has 1 (2%) of the companies. Group F, comprising unusual companies, is different from the Group F of the old companies. The constituent company has a large number of patents in Australia, but a small number in the other countries.

Companies show wide variation in the proportion of their patent portfolio that comes from each country (Supplementary Tables 1 and 2). Thus, for the old companies, US patents make up 45–100%, Australian 0–33%, Canadian 0–29%, European 0–27% and Japanese 0–6%. And for the new companies, the ranges for the US, Australia and Canada are each 0–100%, for Europe 0–33% and for Japan 0–11%.

Discussion

It is often claimed that the chief function of patents is to protect inventions, thereby providing the necessary incentives to the biotech and pharma industry to develop innovative drugs [2]. If this were so, a similar (and larger) number of patents would be protected in all important markets, and fewer in less important ones. In this study, we have tested this hypothesis. The global biotech market is approximately as follows: US 56%, Europe over 24% and Japan 5% (see: <http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=bba69e392879a110VgnVCM100000ed152ca2RCRD&vgnextchannel=b5e57900b55a5110VgnVCM10000071812ca2RCRD&vgnextfmt=default>). The markets in Australia and Canada are each probably smaller than 5%. The global pharma market is broadly similar: US (65%), Europe (21%), Japan (11%), Australia (1%) and Canada (2%) (see <http://www.touchbriefings.com/pdf/790/8-chawla.pdf>).

Even though we group the 103 companies on the basis of different patterns of international patent holdings, we do not find any group that matches the global division of market share. We note that US patents usually, and as expected (both as the largest market and because of its low bar for 'non-obviousness'), dwarf those in all the other markets; however, companies have a tremendous range in the proportion of patents in their portfolios from any given country. In general, Australia has a surprisingly high amount of patenting, whereas that in Japan is negligible.

There could be various reasons why a company obtains fewer patents than might be expected in important markets. These reasons include: (a) Patent applications were rejected because they were invalid owing to prior art. This is improbable as a major reason, because the US is a major patent awarding country (see http://www.wipo.int/ipstats/en/statistics/patents/wipo_pub_931.html#a33). Thus, if being invalid were the cause, it would have been more probable in the US than in some of the other countries investigated. (b) A particular patent office may represent a significant road-block, for reasons of cost, procedure or in terms of a high bar to innovation. The Japanese patent system seems to be such a case (see <http://www.technology.gov/Reports/JapanPatent/pages.pdf>) and this may be a reason for the low number of Japanese patents. (c) All the company's patents are not equally important for protecting its products, and therefore it obtains a smaller number of patents in most territories. This is a possibility, because our earlier work showed that there is poor correlation between the number of patents and the number of products of these companies ([1] and S. Yadav *et al.* unpublished). This reason cannot, however, be the only one, since then one should see a similar number of patents per company per territory. (d) The company lacks the resources, even though it is interested in the market and the patents would be granted if applied for. This might hold for several companies, but not for those which have hundreds of US patents, for instance. (e) The company is not expecting ever to be active in a given market, even in partnership and therefore feels that the expense is not justified. This is a possibility for many companies, especially the smaller ones. (f) Owing to the distance, it is difficult to go after an infringer, so there is not much point in patenting in these other countries. This is also a possibility for smaller companies.

Thus, there does not appear to be a simple answer as to why small drug discovery companies patent as they do. Nevertheless, the data and analysis above should be of interest to companies embarking on drug discovery, whether they are based in the US or in other countries, such as India. Whereas an American start-up company would have easier access to expert opinion on international patenting strategies, the same would not necessarily be the case for companies in countries with a less well-established drug discovery infrastructure. So far no widely used original drug has come out of India and, therefore, there is not much

experience with patenting strategies for new molecules. Nevertheless there is now some original drug discovery work going on in the country, in two kinds of companies. First, the large generic drug companies, such as Ranbaxy Laboratories and Dr Reddy's Laboratories that work on small margins. Second, start-up firms, which are also strapped for cash, because venture capital is not readily available for drug discovery in India as yet. In both cases, therefore, there are minimal funds for patent protection. No doubt as these drug discovery efforts start bearing fruit, the companies will have to have an economical patenting strategy to protect future revenue streams. It is probable that they will want to patent their novel molecules in the major pharma and biotech markets, because it will allow premium pricing in those markets, which may not be possible in the Indian market. It would help them to know what other young drug discovery companies do in the matter of international patenting. Had there been a simple correlation of market size and number of patents, they could have adopted that strategy. We have shown above that this is not, however, the case and further that international patenting strategies of small drug discovery companies are highly variable across countries. Drug discovery companies in India will need to think harder, and gather more information, before deciding which patent applications to file in which country.

Conclusion

In conclusion, we find that a set of 103 US-based biotherapeutic companies with an interest in discovery science have variable patterns of patent holdings across the biotech markets of the world, some of them unexpected. For most companies, the patent holdings are not in proportion to the importance of the country as a biotech or pharma market. There are several possible reasons for this. It is also possible that a combination of reasons holds for several of the companies. A separate study would be required to quantify the contributions of each reason to the patenting patterns of the companies.

Disclosure statement

The authors were not directly supported by industry. Whereas the Institute of Bioinformatics and Applied Biotechnology (IBAB) has collaborated with, and been funded by, several biotech and pharma companies, there is no such rela-

tionship to any company studied herein. IBAB also incubates and mentors young start-up companies, none of which were included in this study.

Acknowledgements

Role of the funding source: Financial support from the Wadhwani Foundation (WF) is gratefully acknowledged. WF has supported our research and teaching activities in general, and has not played any specific role in this study.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at [doi:10.1016/j.drudis.2009.01.010](https://doi.org/10.1016/j.drudis.2009.01.010).

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Teena E. Sebastian,
Chandra Bindu Yerram,
Gayatri Saberwal

*Institute of Bioinformatics and
Applied Biotechnology,*

*NEN-Wadhwani Centre of Excellence in
Entrepreneurship Education,*

*G-05 Tech Park Mall, ITPB,
Whitefield Road, Bangalore 560066, India*