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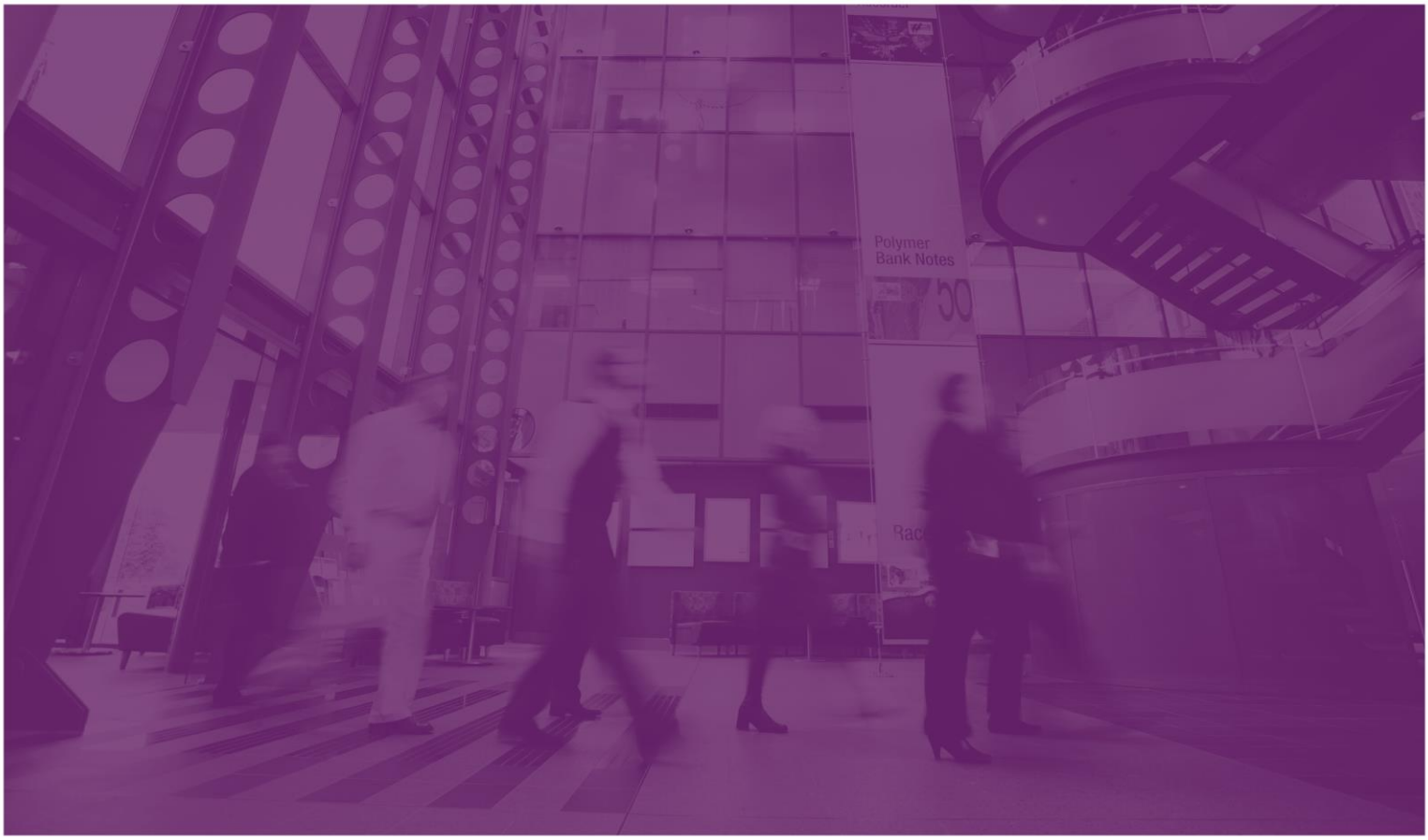
Department of Industry, Innovation and Science

IP Australia

A patent analytics study on the Australian Pharmaceutical Industry

September 2015



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The information contained in this brief has been gathered from global intellectual property (IP) databases and represents a snapshot of patents in the Australian pharmaceutical and biopharmaceutical industry at a particular point in time. It is provided for general information only and should not be relied upon for the purposes of any particular matter. It is not a report on patentability or freedom to operate and should not be relied upon for those purposes.

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Executive summary

The Australian pharmaceutical industry is a substantial contributor to the nation's economy. The industry comprises bio-medical research, biotechnology firms, originator and generic medicines companies and service related segments including wholesaling and distribution.

This report analyses the Australian Pharmaceutical Industry through the lens of intellectual property (IP). It uses the scale and intensity of patent activity to provide an overview of Australian innovation in the area.

The study identifies 2768 pharmaceutical inventions that originate from Australia between 2000 and 2012. Australia ranks 13th in pharmaceutical patents globally, comparable to Switzerland and Israel.

Australia exhibits a positive technological specialisation in the pharmaceutical industry, meaning that pharmaceuticals are a technological focus in Australia. Australia ranks 22nd in technological specialisation globally, which puts it ahead of countries such as Germany and Japan. Within Australia, the majority of inventions (38 per cent) originate in Victoria. The top destinations for pursuing patents are the United States (US), Australia, Europe, Canada and Japan.

Research organisations, such as universities, medical research institutes and the CSIRO are the major filers, making up 40 per cent of applications, followed by small-to-medium enterprises (21 per cent) and foreign corporations (19 per cent). This trend was similar in both Patent Cooperation Treaty (PCT) applications and upon national phase entry in Australia. The top eight applicants were all research organisations, with the University of Queensland, Monash University and the Walter and Eliza Hall Institute topping the list. The first company to appear on the top applicants list is Medvet Science Pty. Ltd. in 9th place, followed by Bionomics Ltd. (10th), Biota Scientific Management Pty. Ltd. (11th) and CSL (12th).

Spin-outs and start-ups from research institutions contribute a significant number of patents, with the top three being Vegenics, Starpharma and Alchemia.

Biologics, which includes peptides, antibodies and antigens, nucleic acid based therapeutics and enzymes, was the major technology area, accounting for 43 per cent of applications. This was closely followed by small molecules with 37 per cent. This is in contrast with the rest of the world during the same period in which small molecules made up 49 per cent of applications compared with 29 per cent for biologics. This indicates that Australia has a particular strength on the development of biological therapeutics.

Patent with multiple applicants, which is an indication of collaborative work, accounted for only 15 per cent of applications. Australians were only slightly more likely to collaborate with other Australians (205 applications) than with foreign applicants (159 applications). The US was the preferred foreign partner, followed by the United Kingdom (UK).

Research organisations were the mostly likely to collaborate, with 22 per cent of their applications having a co-applicant. Only 12 per cent of applications from SMEs and 10 per cent of applications from large firms showed collaboration. Major patent filers such as the University of Queensland, Monash, and the CSIRO have extensive collaboration networks. There was little evidence of extensive collaboration from SMEs or large firms.

Glossary

ANZSIC	Australian and New Zealand Standard Industrial Classification
AusPat	IP Australia's online database containing patent applications filed and granted in Australia
CSIRO	Commonwealth Scientific and Industrial Research Organisation
EPO	European Patent Office
HAN	OECD harmonised applicants' names
IP	Intellectual Property
IPC	International Patent Classification
IPGOD	Intellectual Property Government Open Data
MGC	Murray Goulburn Collective
NPE	National-Phase Entry
OECD	Organisation for Economic Cooperation and Development
QIMR	Queensland Institute of Medical Research
PATSTAT	EPO worldwide patent statistical database
PCT	Patent Cooperation Treaty
REGPAT	OECD 'regionalised' patent database
RSI	Relative Specialisation Index
SME	Small-to-Medium Enterprise
WEHI	Walter and Eliza Hall Institute of Medical Research
WIPO	World Intellectual Property Organization

1 Introduction

This report provides an analysis of the Australian pharmaceutical and biopharmaceutical industry through the lens of patents. By using the scale and intensity of patent activity, identifying areas of technological specialisation, and assessing the level of collaboration, the report provides an overview of pharmaceutical innovation in Australia.

The following questions are explored in relation to the Australian pharmaceutical industry:

- Who are the key filers of Australian pharmaceutical patents?
- What, if any, are areas of technological strength?
- Where are the target markets for pharmaceutical inventions?
- What is the role of collaboration and knowledge transfer in pharmaceutical innovation?
- How is Australia placed in the world market?

1.1 Patents

A patent is a right that is granted for any device, substance, method or process that is new, inventive and useful. Australian patent rights are legally enforceable and give the owner exclusive rights to commercially exploit the invention for a period of up to 20 years. There are two major filing routes for patent applications: international and direct.

The international route involves filing a Patent Cooperation Treaty (PCT) application, which establishes a filing date in all 148 contracting states.[1] Subsequent prosecution at national patent offices, referred to as national-phase entry (NPE), is made at the discretion of the applicant. A patent can only be enforced once it has been granted and a PCT application must enter the national phase to proceed towards grant. Applications generally relating to the same invention but filed in different countries are known as patent families. Patent families enable us to analyse inventive activity regardless of the number of countries in which protection is sought. Direct applications are only filed in the countries of interest.

Through the extraction and analysis of data associated with patent documents, it is possible to measure aspects of inventive activity such as scope, intensity, collaboration and impact. These metrics can be developed across technology sectors and by various units of measurement, such as individuals (inventors), institutions (applicants), regions and countries.

1.2 Definition of Australian pharmaceutical patents

This study focusses on patent applications of Australian origin filed through the PCT route. We classified patents as being of 'Australian origin' when at least one inventor or applicant had an Australian address. States and territories are linked with PCT data according to the address of the patent applicant and inventor. The inventor is the person responsible for the creation of the idea, whilst the applicant is the person or entity that applies for the patent. The inventor and the applicant can be the same entity, or the applicant can be an entity to whom the inventor has assigned their rights, such as the inventor's employer. There may be more than one inventor or more than one applicant on a single application.

[1] WIPO, List of PCT Contracting States

1.3 Time frame for analysis

Patents with a priority date between 1 January 2000 and 31 March 2013 were used in this analysis.[2] PCT applications typically have an 18-month lag from filing to publication; as a result, PCT applications published after March 2013 were not available at the time of extracting data for this report.

The priority date is the most relevant for ascertaining the date of invention. It is the earliest date recorded on patents and therefore allows the comparison of dates unaffected by administrative variations or delays.

1.4 Classification of intellectual property rights

Classification marks and keywords were used to define patents related to the Australian pharmaceutical and biopharmaceutical industry. Patent documents contain an International Patent Classification (IPC) mark that classifies the invention(s) disclosed in the patent. The IPC classifies technology areas into 70,000 different codes. We used these IPC marks to define pharmaceutical patents. A subset of patents relating to the therapeutic use of cells required an additional keyword search. The search methodology can be found in Appendix A.

[2] The Autumn 2014 edition of the PATSTAT database used to identify PCT applications in this study contains all publications to the beginning of September 2014, essentially comprising publications with a priority date up to March 2013. Some documents with later priority dates are published less than 18 months from the priority date and are in the database.

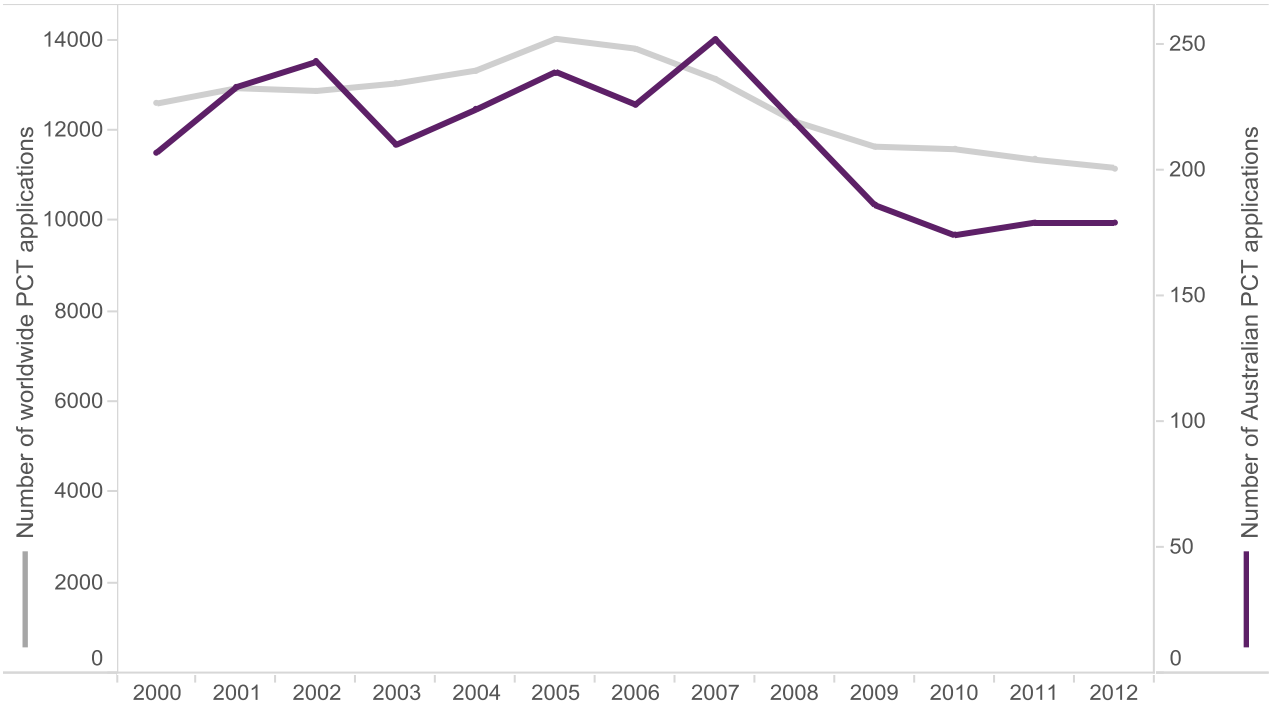
2 Patenting scale and technological specialisation

We identified 2768 PCT applications filed in the pharmaceutical and biopharmaceutical sector between 1 January 2000 and 31 March 2013, each of which had at least one Australian inventor or applicant.

2.1 Patent activity over time

The number of PCT applications filed in the pharmaceutical industry by Australian inventors or applicants (purple line) and the worldwide number of pharmaceutical PCT applications (grey line) is shown in Figure 1. Australian applications generally mirror the world trend, with a decline in applications from 2007 onwards. Whilst we cannot confirm the drop in applications is entirely due to global financial crisis, it does coincide with similar drops in patent applications across other technologies.[3] Unlike other technologies and patent applications in general, the industry appears not to have returned to early-2000s levels. Prior to 2000 there was a steady increase in patent applications from the early 1980s to the mid-1990s, followed by a steep increase in applications from 1995 to 2000. It may be that the decline in applications seen from 2007 onwards is a reversion to a more sustainable level of applications.

Figure 1: PCT applications by priority year in Australian and worldwide

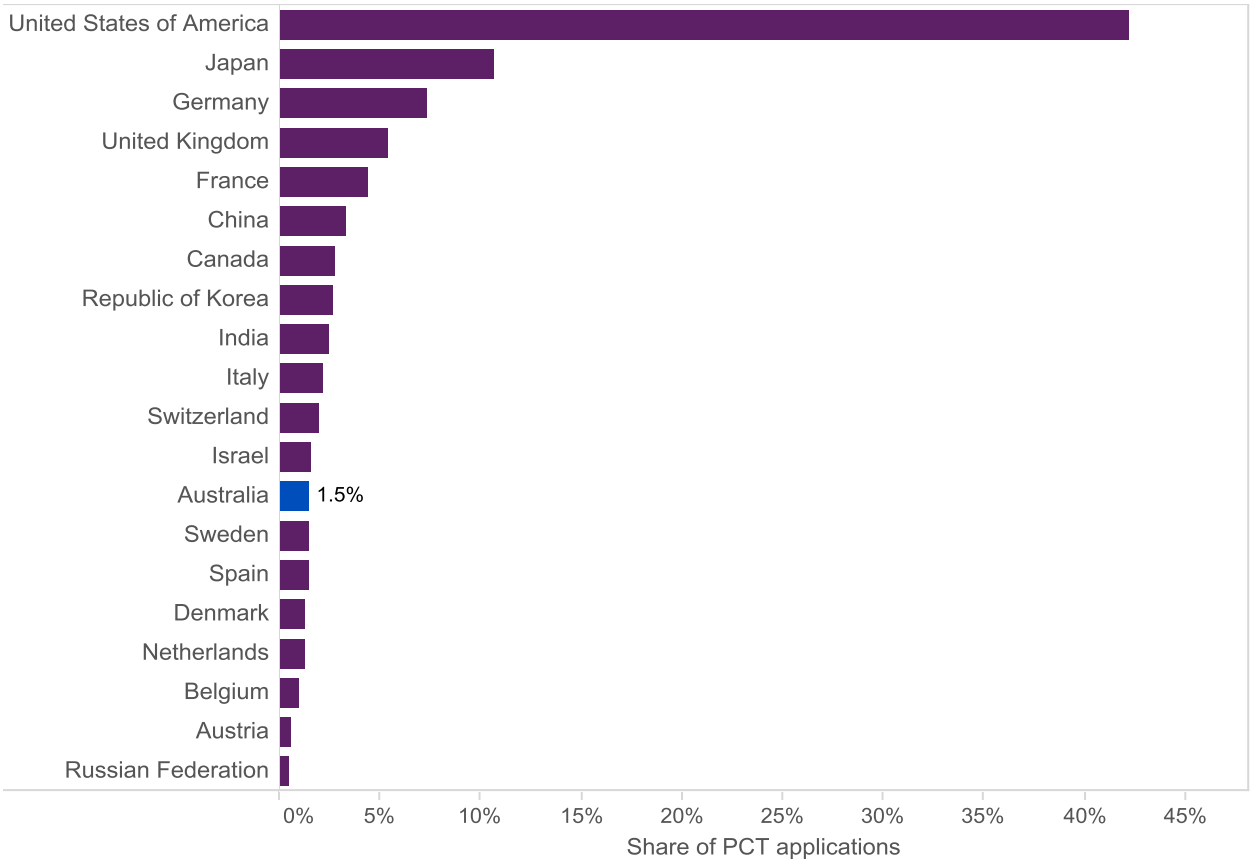


Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; and IP Australia calculations

[3] IP Australia 2014, 'Australian Medical Devices: A Patent Analytics Report'

Figure 2 shows Australia's share of worldwide pharmaceutical patents, based on inventor share. Co-inventorship (multiple inventors) is accounted for using shares. For example, if one PCT application has two inventors, each inventor is assigned an 'inventor share' of 0.5 for that application. In a list dominated by the US, Australia was ranked 13th, with a comparable share of PCT applications to Switzerland and Israel. Australia's share of pharmaceutical PCT applications is 1.5 per cent and is comparable to medical device inventions where Australia ranked 13th with a share of 1.7 per cent. [4]

Figure 2: Share of pharmaceutical inventions across the top 20 countries



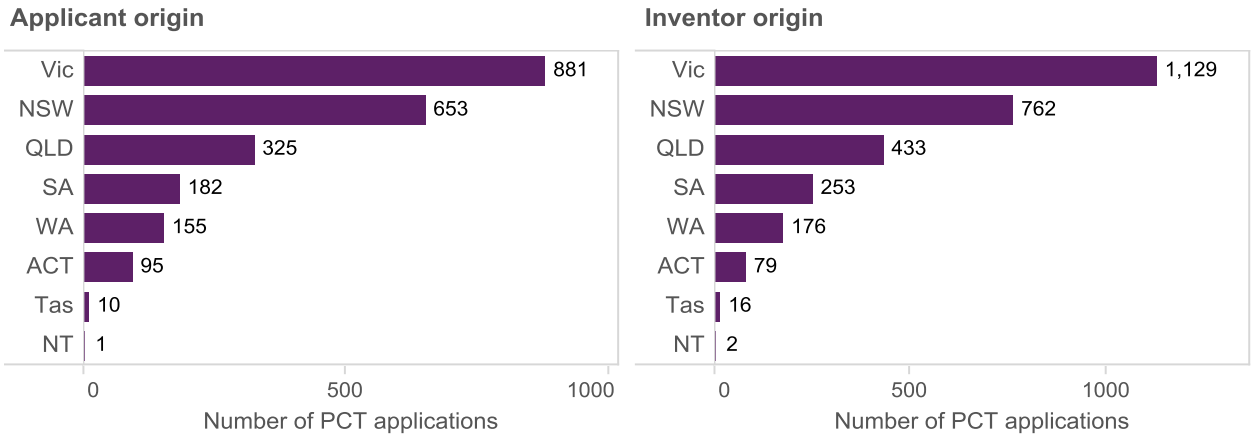
Source: PATSTAT database, Autumn 2014 and OECD, REGPAT database, February 2015

[4] IP Australia 2014, 'Australian Medical Devices: A Patent Analytics Report'

2.2 Origin of innovative activity in Australia

The distribution of pharmaceutical invention origin by Australian state and territory is shown in Figure 3. Figure 3 represents applicant and inventor counts. When there are co-applicants on a patent with addresses in different states, each state is counted as having a patent. For example if co-applicants come from Queensland and New South Wales (NSW), both Queensland and NSW get counted as having one patent each. A similar formula applies to inventors. As can be seen in in Figure 3, Victoria has the most patents, followed by NSW and Queensland. The same trend can be seen with inventor counts on the right of Figure 3. Whilst the vast majority of inventive activity occurs in the capital cities, patents with at least one applicant from Newcastle (41), Geelong (22), the Orana and far west of NSW (12), the Gold Coast (10) and Illawarra (10) all contributed to pockets of patenting activity (data not shown).

Figure 3: Origin of innovative activity in Australia



Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; and IP Australia calcuations

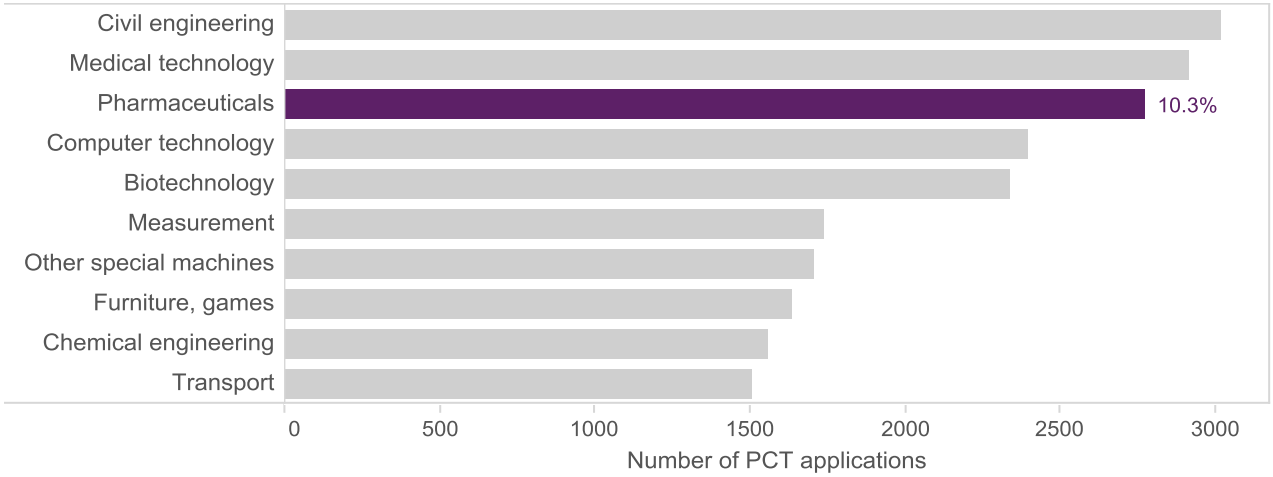
2.3 Technological specialisation

2.3.1 Domestic focus

Figure 4 represents a breakdown of all Australian PCT applications filed between 1 January 2000 and 31 March 2013 by WIPO technology field,[5] to show where the pharmaceutical industry lies compared to other industries in Australia. The pharmaceutical category represents drugs and therapeutic uses of compounds (both synthetic and biological in nature), and is almost identical to the definition of pharmaceuticals used in this report. A small number of applications analysed as pharmaceuticals in this report, those related to the therapeutic use of cells, are included in the biotechnology category in this graph. However, the biotechnology category also includes a much larger range of biological research, such as apparatus for enzymology, fermentation, testing, microorganisms and in vitro uses of the technology.

[5] Schmoch, U 2008, Concept of a Technology Classification for Country Comparisons

Figure 4: Share of pharmaceutical inventions compared to other technology areas in Australia



Source: OECD, REGPAT database, February 2015 and IP Australia calculations

Figure 4 shows that civil engineering and medical technology are the only technology areas with more PCT applications than pharmaceuticals in Australia. Pharmaceuticals accounted for 10.3 per cent of all Australian PCT applications between 1 January 2000 and 31 March 2013.

2.3.2 International focus—Relative Specialisation Index

The Relative Specialisation Index (RSI) is a measure to account for how specialised a country is in a particular technology area. The RSI compares a country's fraction of the total number of pharmaceutical patents filed across all countries, with its fraction of the number of patents across all technologies. The formula is given below:

$$RSI = \log_{10}\left(\frac{{}^{n_i}/_{n_{total}}}{{}^{N_i}/_{N_{total}}}\right)$$

where:
n_i = number of *pharmaceutical* patents from country *i*
n_{total} = number of total *pharmaceutical* patents over the time period
N_i = total number of patents *across all technologies* from country *i*
N_{total} = total number of patents *across all technologies* over the time period

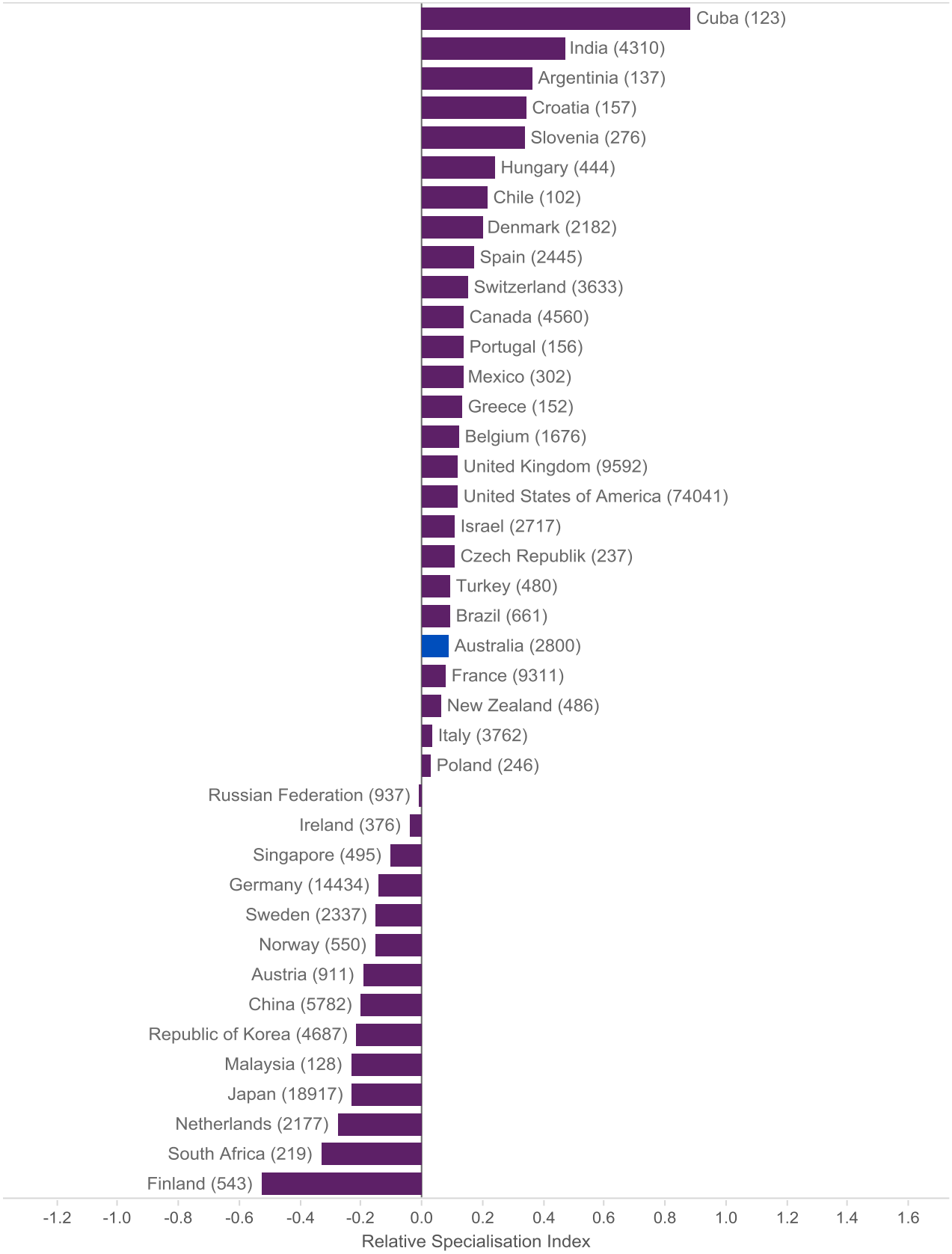
The RSI accounts for that fact that some countries, like US and Japan, file more patent applications than others. The effect of this is to highlight countries that have a greater level of patenting in the searched area than expected from their overall level of patenting, and which would otherwise languish much further down in the lists, unnoticed. The index is equal to zero when the country's share in a given technology field is equal to all patents filed in all fields (no specialisation), and positive when a specialisation is observed.

Figure 5 shows the RSI values by country. Australia exhibits a relative specialisation in pharmaceuticals and ranks in 22nd place. As a comparison, Switzerland, who has a similar share of patents to Australia, ranked in 10th place. Japan and Germany, who ranked 2nd and 3rd respectively in the total number of pharmaceutical patents filed, show a negative specialisation. In comparison with other Australian technology sectors, the pharmaceutical industry is ranked similarly to food (23rd),[6] but was below medical devices which ranked 8th.[7]

[6] IP Australia 2014, 'The Australian Food Industry: A Patent Analytics Report'

[7] IP Australia 2014, 'Australian Medical Devices: A Patent Analytics Report'

Figure 5: Relative Specialisation Index for PCT pharmaceutical applications. Countries with less than 100 pharmaceutical patents are excluded.



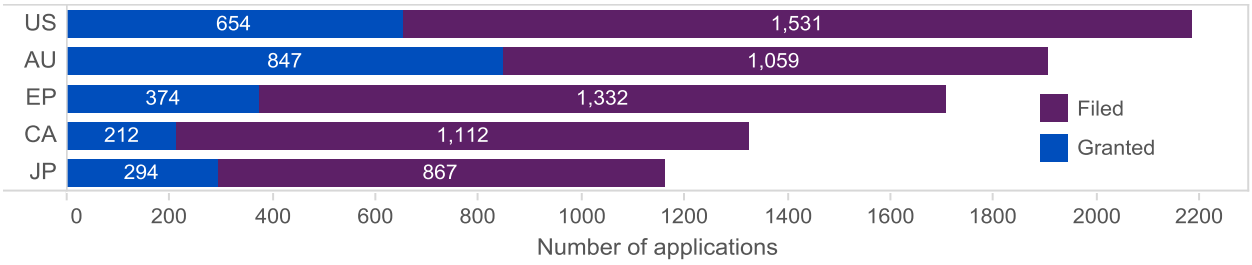
Source: OECD, REGPAT database, February 2015; and IP Australia calculations

3 Target markets

In order to determine the target markets of these pharmaceutical technologies, we can look at the countries where applicants elected to enter national phase. Figure 6 demonstrates the countries with the most prevalent national phase entry and the resultant proportion of grants from these family members.

The predominant jurisdiction of national phase entry is the US, followed by Australia, the European Union, Canada and Japan. The fact that more applicants choose to prosecute their inventions in these jurisdictions is an indication of favourable markets for pharmaceutical products in these countries and the prevalent attitude of that jurisdiction to intellectual property rights. The top three ranked jurisdictions are the same preferred filing jurisdictions in other Australian industries such as the medical device industry.[8] It is interesting to note that China did not rank in the top five jurisdictions for national phase entry, which can again be compared with the medical device industry where China ranked 5th.

Figure 6: Applications and granted patents resulting from national phase entry of pharmaceutical applications



Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; and IP Australia calculations

[8] IP Australia 2014, 'Australian Medical Devices: A Patent Analytics Report'

Box 1: The Generic Pharmaceutical Industry in Australia

A generic pharmaceutical is a product containing the same active ingredient as the originator brand medicine.[9] While only three firms, Alphapharm, Hospira and Aspen, undertake manufacturing or R&D associated with manufacturing generic pharmaceuticals in Australia, many other firms are involved in the marketing of imported final drugs.[10]

Alphapharm is a subsidiary of US-based Mylan Pharmaceuticals and exports generic pharmaceuticals to more than 50 countries including Europe and the US.[11] Alphapharm is a leader in supply of generics to the Pharmaceutical Benefits Scheme (PBS) in Australia with a market share of around 60 per cent.[10] Alphapharm has several patents granted in Australia, which predominantly protect new formulations of known active ingredients. The following two patents relate to products that Alphapharm currently has on the market.

The first is granted patent AU 2009206204 (WO 2009/092129), which protects a new formulation of a pharmaceutical composition comprising duloxetine as the active ingredient. Duloxetine, originally patented by Eli Lilly in 1990 (and marketed as Cymbalta), is prescribed for major depressive disorders and generalised anxiety disorders.[12] Alphapharm manufacture and market Coperin capsules, which contain duloxetine (as hydrochloride) as the active ingredient.[13]

The second is granted patent AU 2008314489 (WO 2009/049354), which protects a matrix controlled-release pharmaceutical formulation comprising desvenlafaxine succinate. Desvenlafaxine is the active metabolite of venlafaxine, an antidepressant developed and marketed by Wyeth (now part of Pfizer) as Efexor.[14] While venlafaxine is now off patent, Pfizer has patented desvenlafaxine, which it now markets as Pristiq.[15] Alphapharm manufacture and market Desfax tablets (desvenlafaxine) in competition with Pristiq.[16]

Hospira is a US based global pharmaceutical and medical device company and is the world's largest producer of generic injectable pharmaceuticals.[17] In 2007, Hospira purchased Mayne Pharma Ltd., an Australian-based specialty injectable pharmaceuticals company, for $2.1 billion.[18] Hospira has manufacturing and research and development sites in Melbourne and Adelaide.[17] Hospira was recently taken over by Pfizer.[19]

Aspen Australia claims to be the largest manufacturer of pharmaceuticals and complementary medicines in Australia. Aspen offers contract manufacturing services in liquids, creams and ointments, solid dose, and packaging.[20] Aspen Australia commenced operations in 2001, acquired Sigma pharmaceutical's business in 2011 and has current sales close to $900 million in Australia and New Zealand. Aspen also exports to a variety of markets in Europe, Asia Pacific, Middle East and Indian Ocean region.[21]

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[9] Harris, T, Nicol, D & Gruen, N 2013, Pharmaceutical Patents Review Report, Canberra

[10] Löfgren, H 2009, 'Generic medicines in Australia: business dynamics and recent policy reform', *Southern Med Review*, 2; 24-28; Sigma divested its pharmaceutical division to Aspen Pharmacare Holdings in 2011

[11] Alphapharm, About us

[12] US 4956388 (Robertson, DW, Wong, DT & Krushinski, JH) 11 November 1990; Drugwatch, Cymbalta

[13] NPS Medicinewise, Coperin Capsules

[14] US FDA, Effexor Wyeth Pharmaceuticals, Inc.

[15] Pfizer, Products

[16] The Pharmaceutical Benefits Scheme, Desvenlafaxine

[17] Hospira, About Hospira

[18] Hospira, Our History

[19] Pfizer, Press Release

[20] Aspen Australia, About Aspen, Manufacturing

[21] Aspen Australia, About Aspen, About us

4 Key applicants

4.1 Applications by entity type

Applicants for pharmaceuticals-related patents include individuals, foreign corporations, large Australian companies, and research organisations such as universities and the CSIRO. In Table 1, we link applicants with the size of their business using IPGOD.[22] IPGOD contains firm-level information on applications by Australian applicants, where those applications have entered national phase. Therefore PCT applicants with no national phase entries in Australia were matched to IPGOD using applicant name to determine firm-level information where possible. Detailed firm-level information is only available for Australian applicants. Some applications had co-applicants, in such cases each applicant was counted as having one application each. For example, a patent having a SME and a large firm as co-applicants was counted as one application for SMEs and one application for large firms. Company size was based on the number of employees, with a company considered to be an SME if it has less than 200 employees.

Of the pharmaceutical PCT applications identified, 1197 (40 per cent) were from research institutions, 629 (21 per cent) were from Australian SMEs, 570 (19 per cent) were from foreign corporations, 424 (14 per cent) from large Australian firms, and the remaining 182 (6 per cent) were from private applicants. Whilst these numbers are based on PCT applications, there is a similar trend when considering national phase entries.

Table 1: PCT applications by entity type

Applicant category	Number of applicants	Number of applications	Percentage of applications (%)
SMEs	290	629	21
Individual	242	182	6
Large Australian Firms	66	424	14
Research Institutions	163	1197	40
Foreign corporations	361	570	19

Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; IPGOD, 2015 edition; and IP Australia calculations

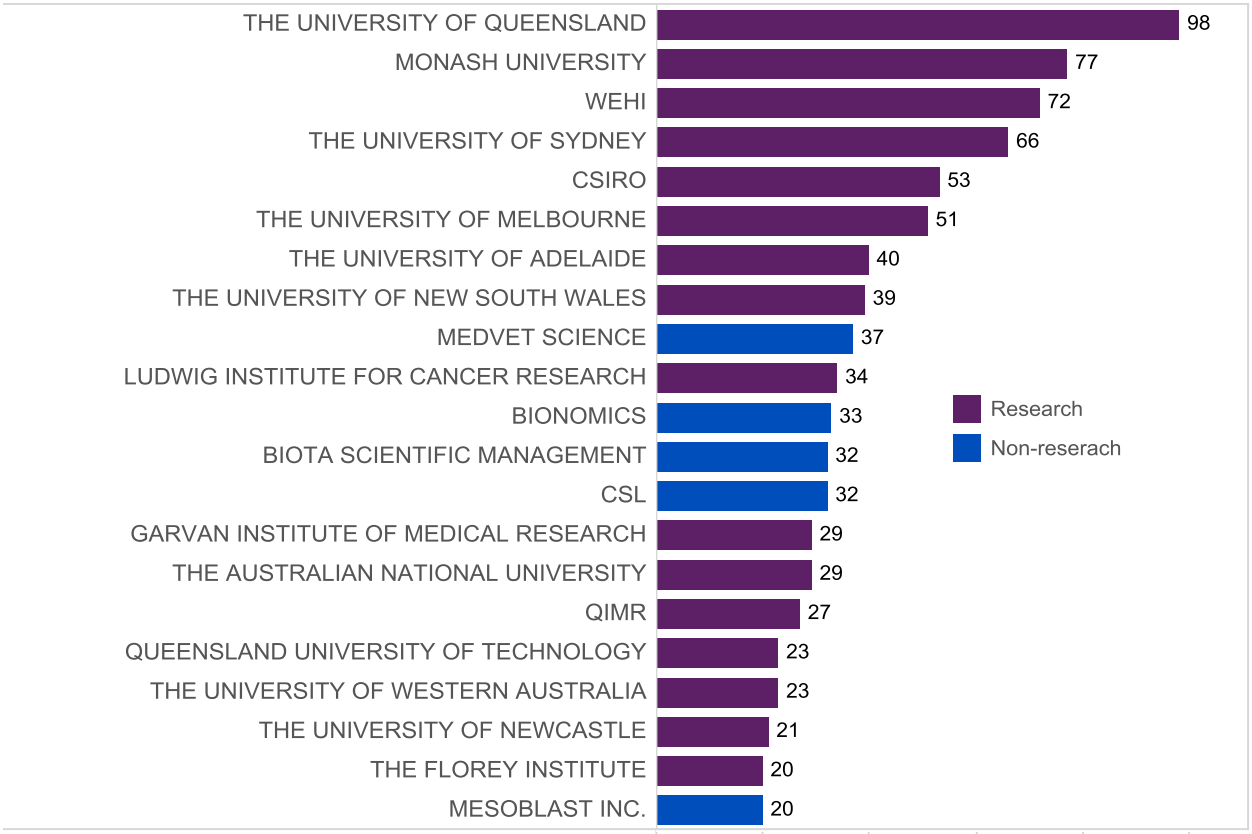
4.2 Top applicants

Figure 7 demonstrates the top applicants. Out of the top 21 applicants, 16 were research organisations and only five were companies. This is a reflection of the focus that Australian research organisations place on pharmaceutical research. Universities and research institutes are conducting most of the basic research and filing PCT applications to cover foundational technologies (Box 2).

The top eight applicants are all research organisations, headed by the University of Queensland, followed by Monash University and The Walter and Eliza Hall Institute of Medical Research (WEHI). The first company appears on the list in 9th place (Medvet Science Pty. Ltd.) followed by Bionomics Ltd. (11th), Biota Scientific Management Pty. Ltd. (12th) and CSL in 13th.

[22] Man, B 2014, 'Overview of the Intellectual Property Government Open Data'. IP Australia Economic Research Paper 02; Julius, TD & Rassenfosse, G 2014, 'Harmonising and Matching IPR Holders at IP Australia' Melbourne Institute Working Paper Series Working Paper No. 15/14

Figure 7: Top Applicants by number of applications



Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; and IP Australia calculations

Box 2: Universities and research institutes are driving the Australian pharmaceutical industry

This case study provides evidence that universities and research institutes are driving the pharmaceutical industry in Australia by filing IP that is commercialised through technology transfer. The Council on Government Relations (COGR) in the US defines technology transfer as 'the handing-off of intellectual property rights from the university to the for-profit sector for purposes of commercialisation.[23] This case study provides evidence that 'technology transfer' is happening in Australia. The research sector files the majority of pharmaceutical PCT applications in Australia (Table 1). Evidence that this IP is being commercialised can be seen from the success of a number of 'start-up' or 'spin-off' companies in translating Australian research. This evidence includes the number of PCT applications being filed by subsidiaries and 'spin-off' companies formed from research institutions (Figure 9). This evidence also includes the success of start-up companies that have resulted from the research of the top PCT filing applicants, The University of Queensland, Monash University and The Walter and Eliza Hall Institute of Medical Research (WEHI) (Figure 7).

The main commercialisation company of The University of Queensland, UniQuest, has been involved with the formation of a number of pharmaceutical start-up companies. Most notably, the spin-off company Admedus which was founded in 2000. Admedus, under the guidance of Professor Ian Frazer, is developing DNA vaccines for the treatment of various infectious diseases

[23] UR Ventures, What is Technology Transfer?

and cancers in humans. Professor Ian Frazer contributed to the development of the Gardasil® vaccine against cervical cancer,[24] which is now used globally with more than 97 million doses distributed in 120 countries.[25]

Monash University's pharmaceutical start-up companies include Acrux and Relevare Pharmaceuticals.[26] Acrux is a developing a range of pharmaceutical products for global markets using innovative technology to administer drugs through the skin.[27] In 2010, Acrux signed a global deal with US based pharmaceutical company Eli Lilly for the commercialisation of transdermal testosterone solution, AXIRON©.[28] The US Food and Drug Administration (FDA) approved a new drug application for AXIRON©, making it the first testosterone replacement product authorised for administration via the armpit.[28] In 2010 Acrux achieved a record revenue result of A$55 million and Acrux's marketing partner launched AXIRON© into the billion-dollar US market in early 2011.[28] Relevare Pharmaceuticals Ltd. develops therapies to treat chronic and acute pain. Relevare Pharmaceuticals Ltd. was formerly known as CNSBio Pty. Ltd. and changed its name to Relevare Pharmaceuticals Ltd. in April 2010.

WEHI research has resulted in the establishment of nine start-up companies.[29] WEHI pharmaceutical start-up companies include MuriGen Therapeutics Ltd., ImmusanT and Catalyst Therapeutics.[30] MuriGen Therapeutics Ltd. is developing drugs across a number of therapeutic areas including cancer, arthritis, thrombocytopenia and inflammation. In particular, Murigen Therapeutics is developing patent protected Bcl-2 family proteins as anti-apoptotic agents.[31] ImmusanT is developing a treatment and a set of diagnostic and monitoring tools to manage patients with coeliac disease.[32] ImmusanT's peptide-based therapeutic vaccine, Nevax2® has completed Phase I clinical trials, and clinical development of Nevax2® in patients with celiac disease is underway in the US and Australia.[33] Catalyst Therapeutics Pty. Ltd. was formed by a partnership between WEHI and SYNthesis med chem Pty. Ltd.[34] Catalyst Therapeutics is funding two projects. The first project is aimed at generating drug-like small molecule inhibitors of a protein implicated in the development of leukaemia and several other cancers.[35] The second project aims to develop an inhibitor of necrosis pathway protein which would have therapeutic benefit in the treatment of inflammatory diseases such as psoriasis.

Further evidence that IP is being commercialised in the Australian pharmaceutical industry is the fact that many of the top companies filing PCT applications in Australia (Figure 8) had their origins in research institutes or universities. For example, Medvet Science was formerly the commercial arm of the Institute for Medical and Veterinary Science (IMVS) in South Australia, Bionomics was founded based on research from the Women and Children's Hospital in Adelaide[36] and the University of Melbourne, and Mesoblast was founded partly based on research from the Hanson Institute in Adelaide.[37]

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[24] University of Queensland, Cancer Studies

[25] University of Queensland, Immunology and Infectious Diseases

[26] Monash University, Spin-out companies

[27] Acrux, About Acrux

[28] Monash University, Acrux (accessed 12 July 2015)

[29] Walter and Eliza Hall Institute of Medical Research, Business Development

[30] Walter and Eliza Hall Institute of Medical Research, Start-up companies

[31] MuriGen Therapeutics, Pipeline

[32] ImmusanT, About Us

[33] ImmusanT 2011, 'Coeliac disease vaccine shows promising results in Phase I trial' 8 May 2011

[34] Walter and Eliza Hall Institute of Medical Research, Start-up companies

[35] Catalyst Therapeutics, Strategic alignment

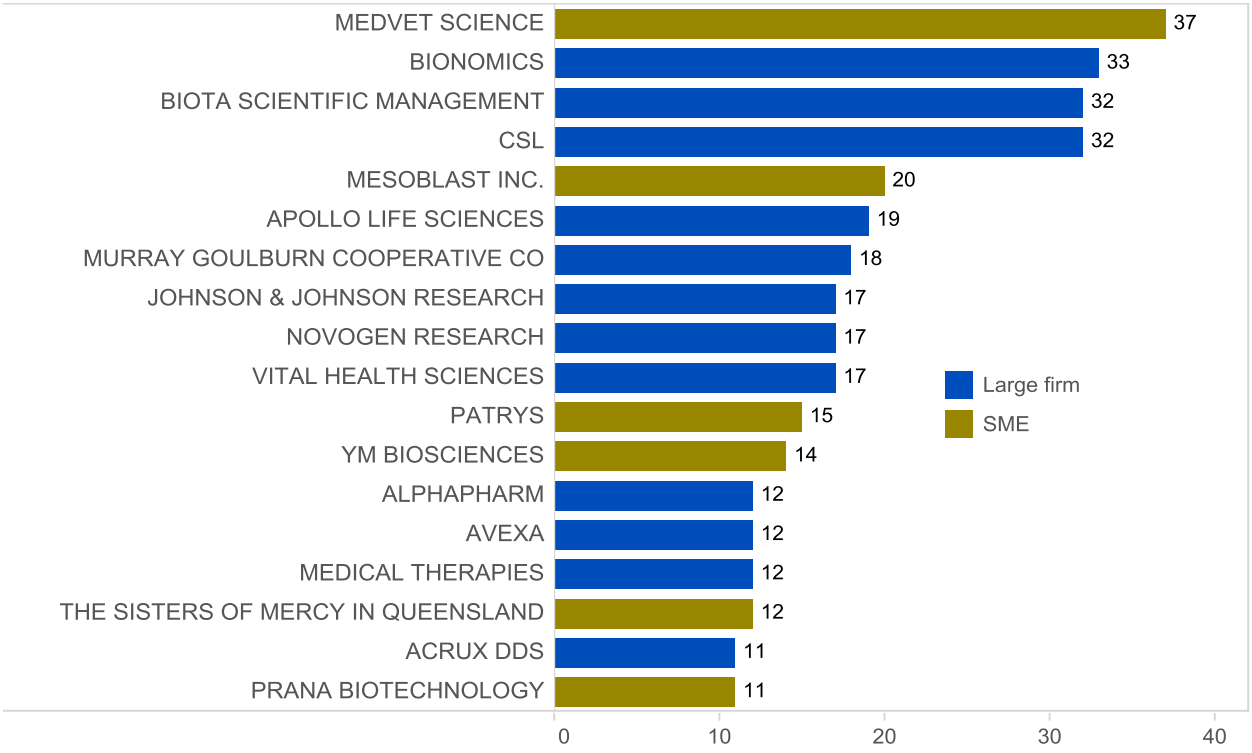
[36] Bionomics, About

[37] Mesoblast, Annual Report 2010

4.3 Top companies

Figure 8 shows the top 18 companies filing PCT applications, broken down by company type. Large firms accounted for 12 of the top 18 applicants with small-to-medium enterprises (SMEs) only accounting for six. Large foreign pharmaceutical company Johnson & Johnson is on the list as at least one Australian inventor appears on their patents. Large Australian firms that make the list include Bionomics Ltd., Biota Scientific Management Pty. Ltd., CSL, Novogen Research (Box 3), Alphapharm (Box 1), Avexa and Cellmid (formally Medical Therapies Ltd.).

Figure 8: Top Pharmaceutical PCT Firms



Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; and IP Australia calculations

Bionomics, based in Adelaide and founded using research from the Women and Children's Hospital in Adelaide and the University of Melbourne, is a biopharmaceutical company dedicated to making better treatments for cancer and central nervous system disorders such as anxiety, depression and Alzheimer's Disease.[38]

Biota Scientific Management Pty. Ltd., formally based in Melbourne, is the research and development arm and a wholly-owned subsidiary of Biota Holdings (Biota).[39] In conjunction with Monash University, Biota is best known for the development of Relenza®, the first-in-class drug commonly used to treat Swine and Avian Flu. Biota is in the process of closing its Australian operations.

The CSL Group, based in Melbourne, develops and manufactures vaccines and plasma protein biotherapies. CSL's areas of expertise include plasma products, vaccines and pharmaceuticals,

[38] Bionomics, About

[39] Professional Advantage, Biota Turns to QlikView for Analytics and Reporting Support Following Awarding of US$231 Million Grant

and research and development. [40] CSL has facilities in Australia, Germany, Switzerland and the US. CSL employs over 13,000 employees working in 27 countries.

Alphapharm is a generic drug manufacturer with manufacturing facilities in Brisbane. It is the largest single supplier of medicines to the pharmaceutical benefits scheme (PBS) (Box 1).

Avexa is a spinout of AMRAD (later Zenyth Therapeutics who was taken over by CSL). Four Melbourne research institutes with financing form the Victorian State Government founded AMRAD.[41] Avexa's key projects include apricitabine (ATC) for the treatment of drug resistant HIV, an HIV integrase programme and an antibiotic programme for antibiotic-resistant bacterial infections.[42]

Cellmid (formally Medical Therapies Ltd.) develops therapies and diagnostic tests for a number of cancer indications, in particular solid tumours. Cellmid's most advanced development programmes involve using anti-midkine antibodies in addition to commercialising midkine as a biomarker for the early diagnosis and prognosis of cancer.[43]

Box 3: Novogen

Novogen Ltd. is an Australian publically owed drug-development company based in Sydney that was formed in 1994. [44] The Novogen group includes the US-based CanTx Inc., a joint venture company with Yale University, and trades on both the Australian Securities Exchange (ASX) and NASDAQ. [45]

Novogen research is especially focused on the therapeutic fields of oncology, degenerative and regenerative diseases and autoimmune diseases. [46] The oncological area is structured around two areas; [47] Super-benzopyrans (SBPs) [48] and anti-tropomyosins (ATMs). [49] SBPs are drug compounds based upon benzopyran ring structures that are commonly found in nature. [50] SBP compounds target the abnormal movement of protons across intra-cellular membranes. ATM compounds are a new class of cancer drugs that target the internal structure of tumour cells by targeting the protein tropomyosin. [51] Tropomyosin molecules pair with another protein called actin to organise the internal structure of all cells in the body including cancer cells.

Currently, Novogen is developing three oncology drugs, Cantrixil, Trilexium and Anisina with the intention of making them clinically available at some point in 2016. [52] Anisina in particular has recently received orphan drug designation from the US FDA to treat neuroblastoma. [53] One of the most recent patents filled by Novogen, WO 2010/012037, relates to compounds that are 6-substituted isoflavonoid derivatives.

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[40] CSL, About CSL

[41] Encyclopedia of Australian Science, AMRAD Corporation Ltd. (1986 - 2005)

[42] Avexa, About us

[43] Cellmid, About Us

[44] ASX, NRT: Novogen Ltd

[45] PR Newswire, 'Novogen Announces Breakthrough Discovery in the Treatment of Melanoma' 16 December 2014

[46] Bloomberg Business, Novogen Ltd.

[47] Novogen, The Oncology Platforms

[48] Thayer, AM 2015, Pharmaceutical Outsourcing, *Chemical & Engineering News*, 9 March 2015, 93(10), 11-19

[49] Gunning, PW et al. 2013, 'A Novel Class of Anticancer Compounds Targets the Actin Cytoskeleton in Tumor Cells' *Cancer Res,* 73(16), 5169-5182

[50] Novogen, Super-benzopyran drug technology

[51] Phillips, N 2013, Sydney team develop new cancer drug, Sydney Morning Herald, 15 August 2013

[52] Former CEO: Novogen in sound position, News.com.au, 22 July 2015

[53] 'Novogen gets FDA orphan drug status for Anisina to treat neuroblastoma', Production & Manufacturing Process & Production, 17 July 2015

The top twenty companies also include SMEs such as Medvet, Mesoblast, Patrys, YM Biosciences and Prana Biotechnology.

Medvet Science Pty. Ltd. (trading as Medvet) was formally the commercial arm of the Institute for Medical and Veterinary Science (IMVS) in South Australia. In 2008, IMVS merged with the pathology departments of two other Adelaide hospitals and was renamed SA Pathology.[54] Medvet Science Pty. Ltd. is a private company whose sole shareholder is a division of the South Australian government. Medvet now conducts workplace drug and alcohol testing, food and environmental testing as well as providing national on-site vaccination services but continued to fund medical research until 2014.[55] As such, Medvet Science Pty. Ltd. is not a typical small start-up and only falls into the SME category due to its current status.

Mesoblast is developing biotherapeutics based on its proprietary cell-based and protein technologies.[56] Mesoblast was founded, after acquiring adult stem cell technology from the Hanson Institute and Medvet, both in Adelaide.

Patrys is focussed on the development of human antibodies for the treatment of cancer and is headquartered in Melbourne.

YM Biosciences merged with Melbourne-based Cytopia in 2010.[57] Cytopia developed small molecule tyrosine kinase inhibitors to target cancer, and was founded based on research conducted at the Ludwig Institute for Cancer Research in Melbourne.[58]

Prana Biotechnology develops therapies to treat neurodegenerative diseases. Their lead drug candidate is being developed for the treatment of Alzheimer's and Huntington's diseases. Prana Biotechnology was incorporated in Melbourne in 1997.[59]

Other companies on the list include Apollo Life Sciences, which no longer operates as a biotechnology company, the Murray Goulburn Co-operative (Box 4), Vital Health Sciences which sells vitamins and supplements, the Sisters of Mercy Corporation from Queensland which files patents on behalf of the Mater Medical Research Institute (MMRI) and Acrux Drug Delivery Solutions (Box 2).

Box 4: Murray Goulburn Co-operative

Murray Goulburn Co-operative Co. Ltd. (Devondale Murray Goulburn) is an agricultural cooperative formed in 1950 which has grown to become the largest processor of milk in Australia and the nation's largest exporter of processed food.[60] Murray Goulburn Co-operative ranks seventh in the top pharmaceutical firms filing PCT applications (Figure 8). As a major milk and dairy producer in Australia, Murray Goulburn Co-operative has filed PCT applications relating to methods of treatments using products derived from milk.

On example is WO 2013/166557, which provides a method of treating cachexia by administering angiogenin. Angiogenin is a potent stimulator of new blood vessels and can be provided by the fractionation of milk or milk products. Another example is WO 2011/113100, which provides a method of treating a bone disorder by administering a basic growth factor extract derived from a milk product.

[54] SA Pathology, Our History

[55] Medvet, About Us

[56] Mesoblast, Company Overview

[57] delisted Australia, Cytopia Ltd (CYT), 5 February 2010

[58] Catalyst Therapeutics, Management

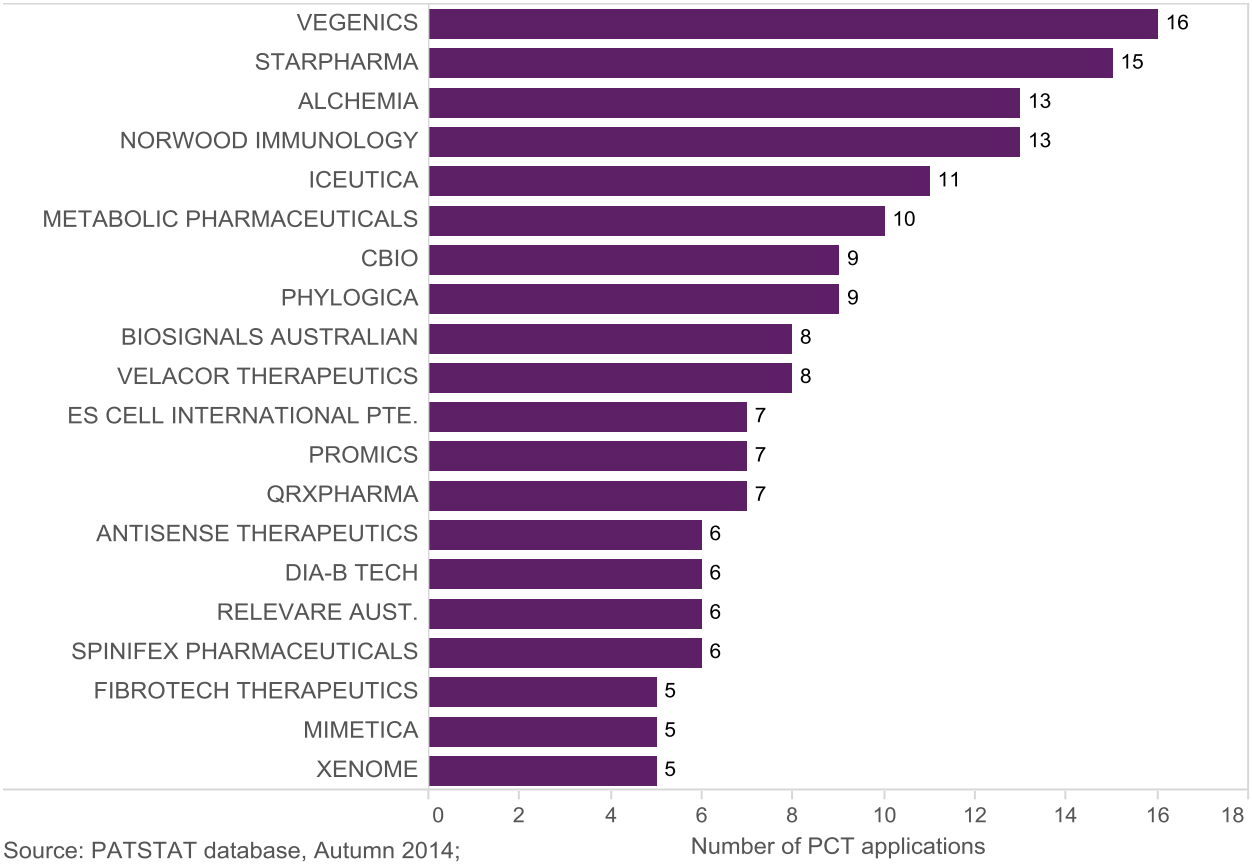
[59] Prana Biotechnology, About Prana Biotechnology

[60] Devondale Murray Goulburn, Our heritage

4.4 Top subsidiaries and spin-outs

Figure 9 shows the top applicants that are subsidiaries or spin-outs from universities or research institutions. These companies were identified by the National Survey of Research Commercialisation (NSRC). This survey, conducted on a biennial basis, questions publicly funded organisations on various issues in order to assess the effectiveness of government funding levels. These metrics include staffing levels, new spin-offs launched since the last survey and levels of patenting and contract research activity.[61]

Figure 9: Top subsidiaries and spinouts from research institutions



Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; and IP Australia calculations

Vegenics developed angiogenic and lymphangiogenic molecules that include vascular endothelial growth factors (VEGF).[62] Vegenics was founded in May 2006 and originated from a collaboration between the Ludwig Institute for Cancer Research and Licentia Ltd., the commercial arm of the University of Helsinki. Vegenics was acquired by Circadian in August 2008.[63]

Starpharma, based in Melbourne and a spin-out from the CSIRO, is a world leader in the development of dendrimer-linked drugs and products for pharmaceutical and life science applications, with a focus on the prevention of sexually transmitted infections.[64]

[61] Department of Industry and Science, National Survey of Research Commercialisation

[62] Bloomberg Business, Company Overview of Vegenics Pty. Ltd.

[63] Circadian, Vegenics: Owner of VEGF Technology

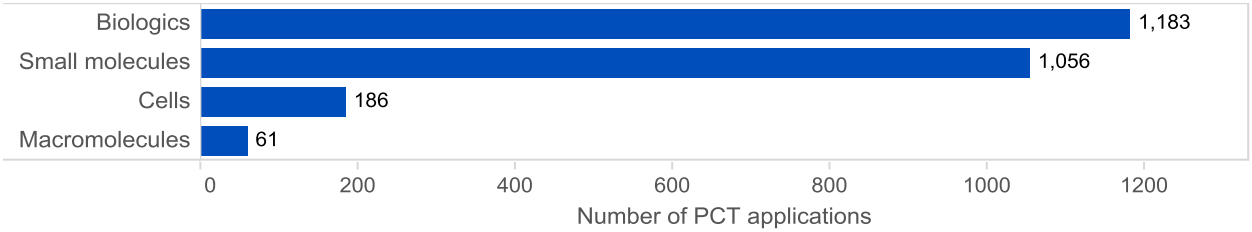
[64] Starpharma, About us

5 Pharmaceutical technologies originating from Australia

For the purposes of this report we developed a technology breakdown of PCT applications from Australia based on particular IPC marks or combinations of IPC marks. Patents were broken down into the broad technology classes of biologics, small molecules, cells and macromolecules. For example, a patent containing a mark relating to a peptide or an antibody was classified as a biologic. Chemical agents were broken down into small molecules and macromolecules. The "Cells" category specifically refers to the use of cells as therapeutic agents, for example the delivery of stem cells. A detailed breakdown of the IPC marks and the technology breakdown can be found in Appendix B and Appendix C.

Figure 10 shows that there is a slight focus on biologics in Australia (43 per cent of applications) when compared with small molecules (37 per cent of applications). This is in contrast with the rest of the world during the same period in which small molecules made up 49 per cent of applications compared with 29 per cent for biologics (data not shown). This indicates that Australia has a particular strength on the development of biological therapeutics. The other categories were similar to the rest of the world. It should be noted that 282 applications were not included in this breakdown as they fell into other categories including diagnostics.

Figure 10: Australian PCT applications by technology category



Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; and IP Australia calcuations

In the remainder of this chapter will provide further detail into the major areas shown in Figure 10. For the purposes of this report each technology area is broken into subcategories:

- new pharmaceuticals
- treatment, which covers using known pharmaceuticals for a new purpose and methods of using pharmaceuticals
- formulations, which includes mixtures of known pharmaceuticals in combination with other compounds such as stabilisers, surfactants and buffers
- diagnostics, which includes pharmaceuticals used in the diagnosis of disease states or conditions.

5.1 Technologies by entity-type

Universities and research institutes file the most pharmaceutical PCT applications in all of the four technology types with biologics accounting 57 per cent and small molecules accounting for 33 per cent of those applications (Table 2). Foreign applicants file the second largest number of PCT applications with small molecules accounting 48 per cent and biologics accounting for 43 per cent of those applications. SMEs file only slightly less PCT applications than foreign applicants with a similar split of applications between non biologics (48 per cent) and biologics (41 per cent). Table 2 indicates that the research sector is filing nearly double the amount of biologics applications than small molecules applications whereas foreign applicants, Australian SMEs and large Australian firms are all filing similar amounts of biologics and small molecules applications. These results are not surprising as the research sector is predominantly involved with identifying new gene targets and biological pathways but then often requires collaboration with private industry to develop targeted drugs.

Table 2: Technologies by entity type.

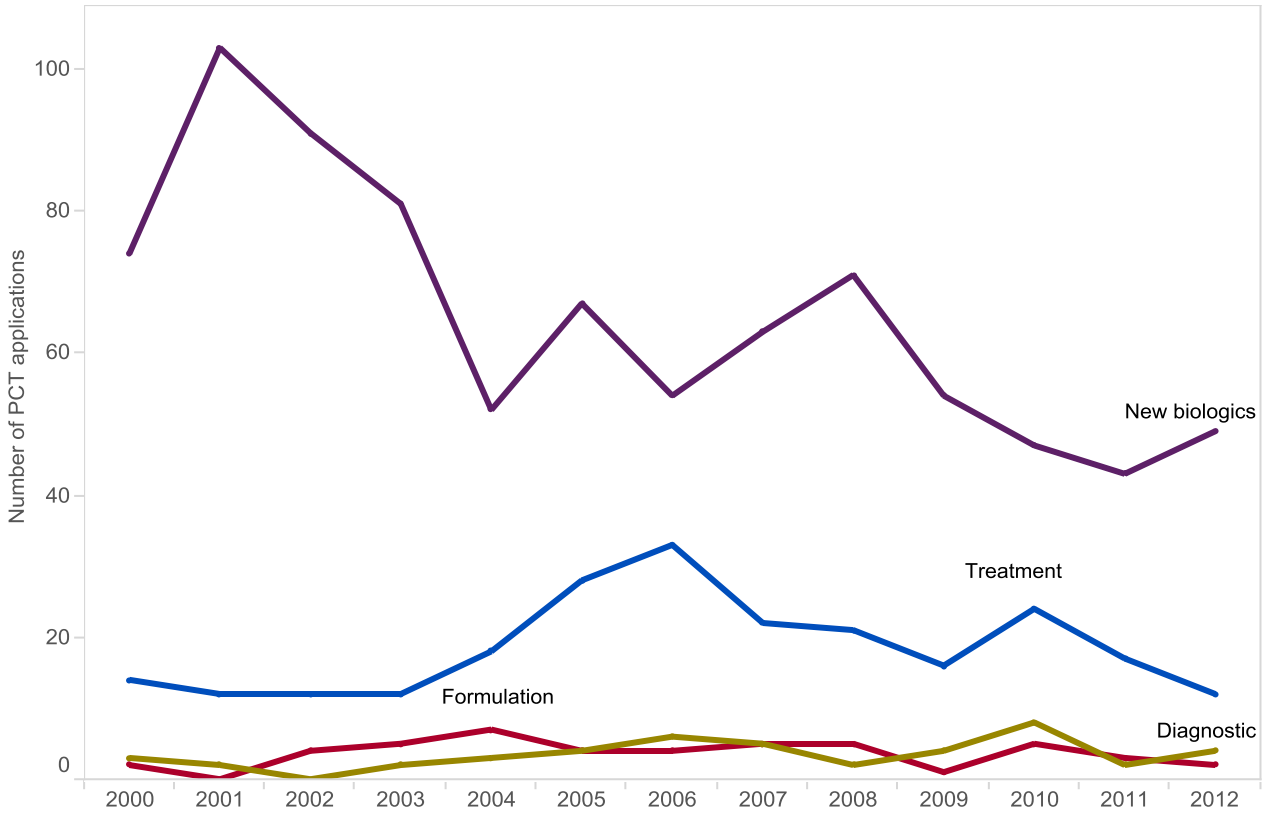
Applicant category	Biologics	Small molecules	Cells	Macromolecules
Australian SMEs	216	253	44	19
Large Australian Firms	179	175	19	3
Research Institutions	634	369	84	33
Individual	48	77	11	3
Foreign corporations	232	257	42	5

Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; IPGOD, 2015 edition; and IP Australia calculations

5.2 Biologics

Included within the scope of biologics are peptides, antibodies and antigens, nucleic acid based therapeutics and enzymes. Figure 11 shows biologics patent filing over time by technology subcategory. It shows the major focus is the development of new biologics (72 per cent), followed by treatment applications (20 per cent) and the remainder being formulations and diagnostics (8 per cent). The dips to the x-axis in formulations and diagnostics in Figure 11 indicate that no formulation patents were filed in 2001 and no diagnostic patents were filed in 2002.

Figure 11: Filing trend—biologics

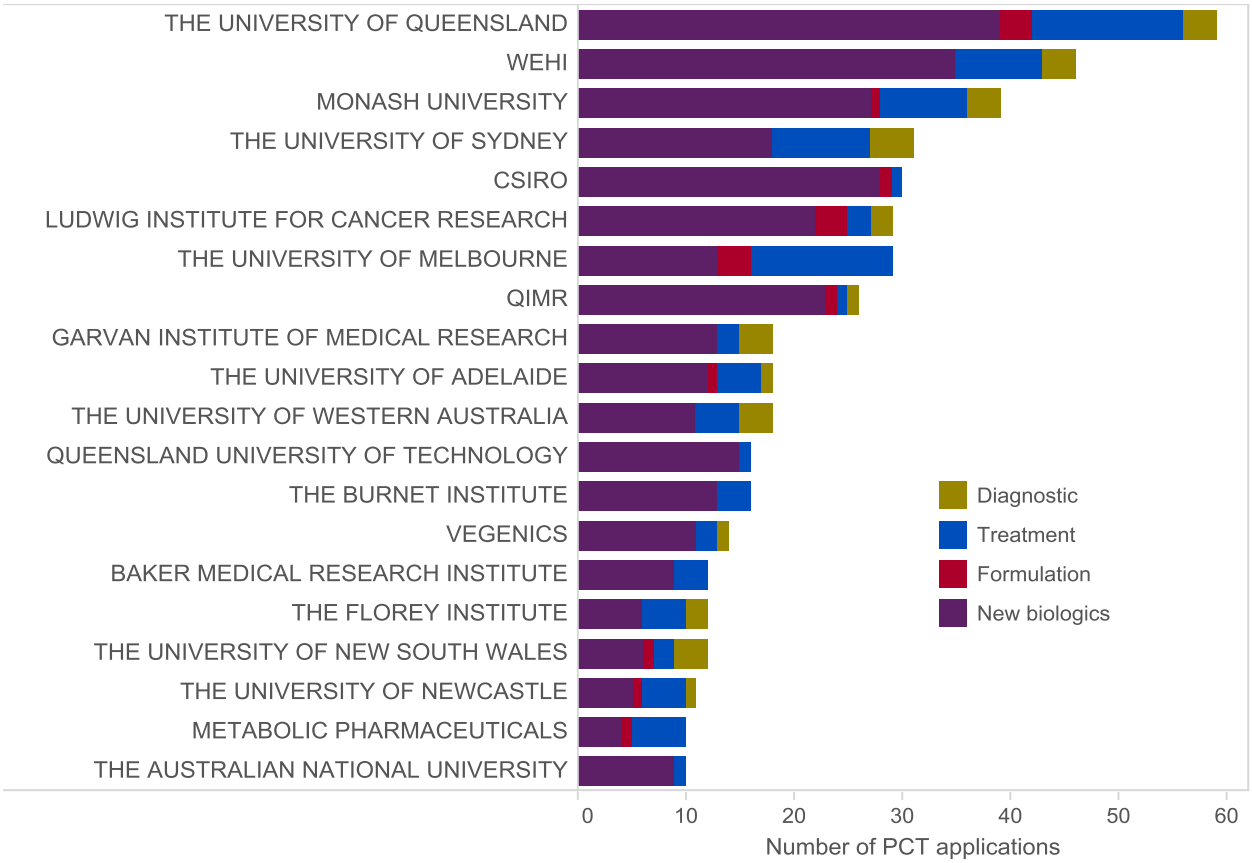


Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; and IP Australia calculations

New biologics peaked in 2001, with application rates remaining steady since 2004. The declining trend relating to new biologics from the early 2000s to a levelling off in 2004 is mirrored by the rest of the world. The fact that the treatment subcategory increased slightly from the early 2000s (running contrary to the world trend), could be related to the development of methods of treatment based on genetic information obtained from the publication of the human genome.

Figure 12 shows the top research applicants in the biologics category and the technology subcategories they file in. It shows the research sector is most active in filing patents for biologics in Australia with most of those patents relating to new biologics.

Figure 12: Top research applicants in biologics



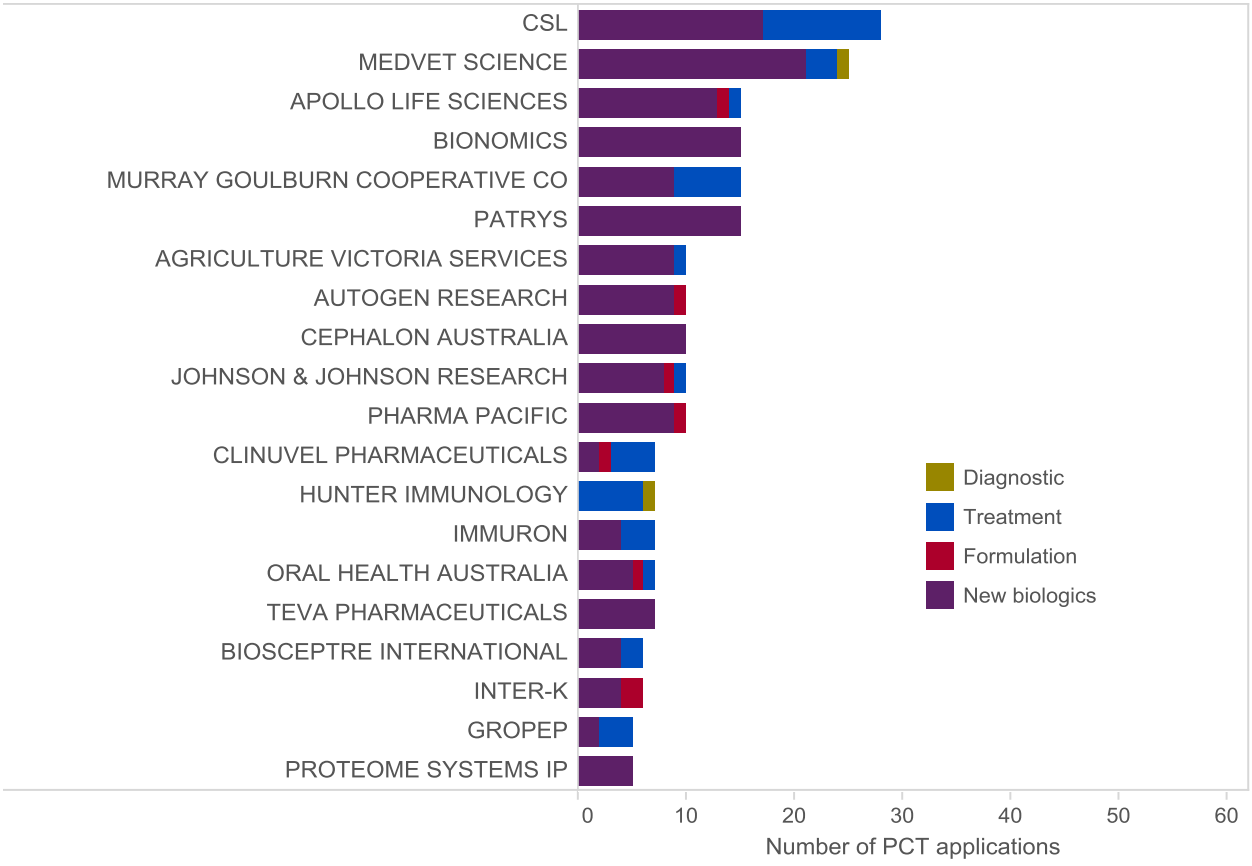
Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; IPGOD, 2015 edition; and IP Australia calculations

The University of Queensland, WEHI and Monash University topped the filing of PCT applications in the biologics technology category. In the new biologics subcategory the top filers were the University of Queensland, WEHI and the CSIRO. The University of Queensland, the University of Melbourne and the University of Sydney ranked highest for the treatment category, which comprises new methods of treatment using known biologics. The University of Queensland, the University of Melbourne and the Ludwig Institute for Cancer Research ranked equal highest in the formulation category which comprises new formulations of biologics.

The Ludwig Cancer Research Institute is an international not-for-profit organisation established by American businessman Daniel K Ludwig in 1971. The Ludwig Institute conducts its own research and clinical trials making it a bridge between basic research and cancer care. [65] In Australia, it was established by collaboration between the Royal Melbourne Hospital, the University of Melbourne and WEHI. In 2013 the fund restructured its international operations, with the Australian branch moving to be part of the Olivia Newton John Cancer Research Centre.

[65] Ludwig Cancer Research, About us

Figure 13: Top company applicants in biologics



Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; IPGOD, 2015 edition; and IP Australia calculations

The top two companies filing biologics patents overall were CSL and Medvet Science Pty. Ltd., followed by Apollo Life Sciences, Bionomics, the Murray Goulburn Co-operative Co. Ltd. (Box 4) and Patrys Ltd. (Figure 13).

CSL, the Murray Goulburn Co-operative Co. Ltd. and Hunter Immunology are the highest ranked companies under the treatment subcategory. Hunter Immunology was incorporated in 2003 and was involved in research and development of immunotherapeutics and vaccines for treatment of Chronic Obstructive Pulmonary Disease (COPD). Hunter Immunology's lead product (HI-164OV) is an orally administered immunotherapeutic, which has completed a Phase IIb clinical trial for the treatment of COPD.[66] In 2012, Hunter Immunology merged with another Australian company (Probiomics Ltd.) with the merged entity renamed Bioxyne.[67]

Medvet Science Pty. Ltd. and CSL are the top two companies for PCT filings in the new biologics category. Bionomics and Patrys Ltd. were ranked equal third for new biologics. Patrys is a company developing natural human antibodies for the treatment of cancer.[68] Patrys' headquarters are in Melbourne, their main R&D centre is in Würzburg, Germany, and their antibody manufacturing facility is in the U.S. Inter-K was the highest ranked company for filing new formulations of biologics. Inter-K was founded in Newcastle, NSW, in 2002 following a discovery of a mechanism which regulated the growth of human cancer cells.[69]

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[66] Bloomberg Business, 'Company Overview of Hunter Immunology Pty. Ltd.

[67] Biospace, News, 'Australian Drug Developer, Hunter Immunology Ltd, Set to List on ASX',

[68] Patrys, About Us

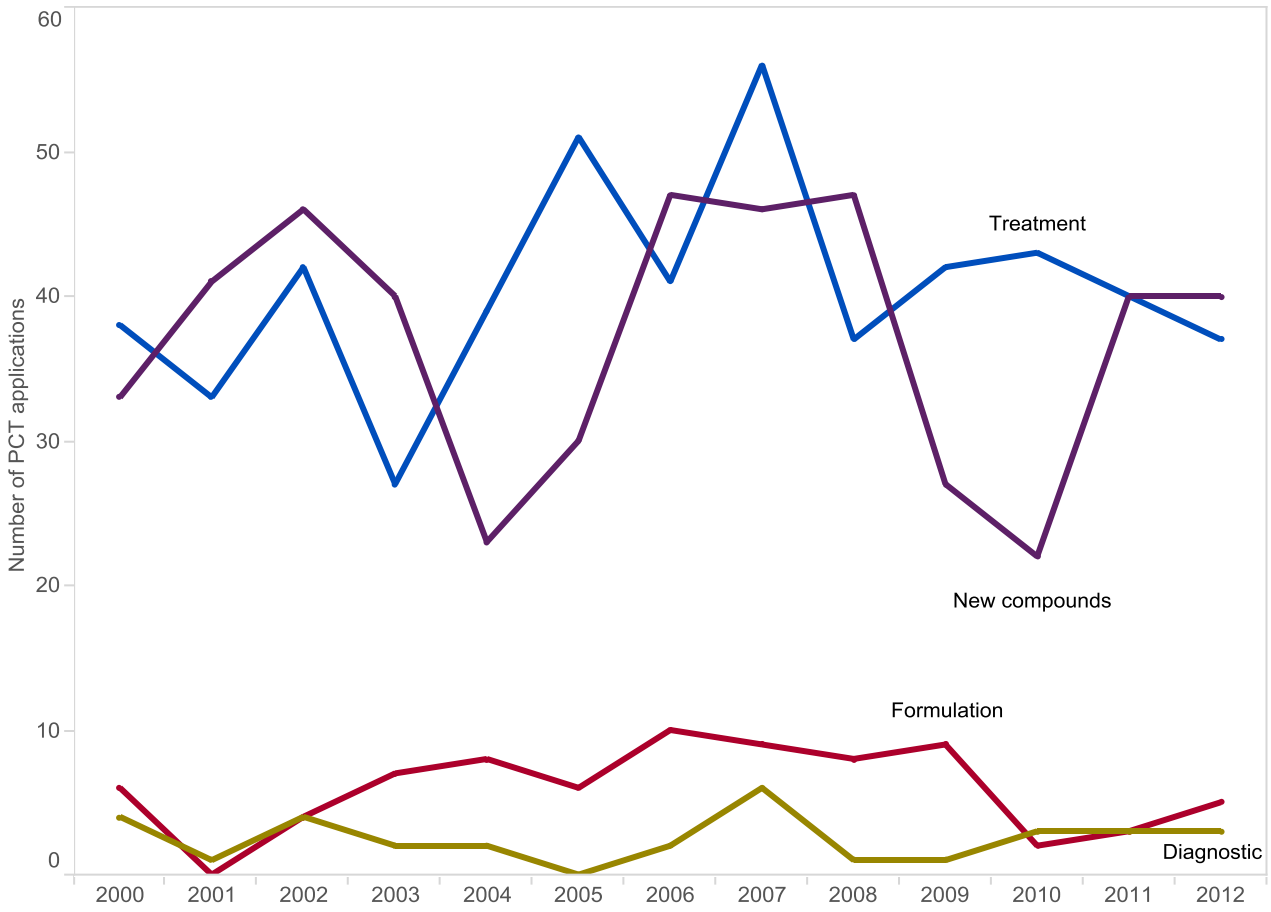
[69] AiHit Data, Inter-K Company Overview

5.3 Small molecules

Small molecules are a broad category that includes within its scope small chemical entities and small sugars. The filing trend for small molecules is shown in Figure 14.

Figure 14 shows the breakdown of filings over time in the small molecules technology category. New compounds make up approximately 43 per cent of applications, slightly behind the treatment category with 47 per cent. The remaining 10 per cent is made up of formulations and diagnostics. These results show a lower portion of new compounds being developed (43 per cent) compared to new biologics (72 per cent) but higher new uses of old compounds (47 per cent) compared to new uses of old biologics (20 per cent).

Figure 14: Filing trends—small molecules

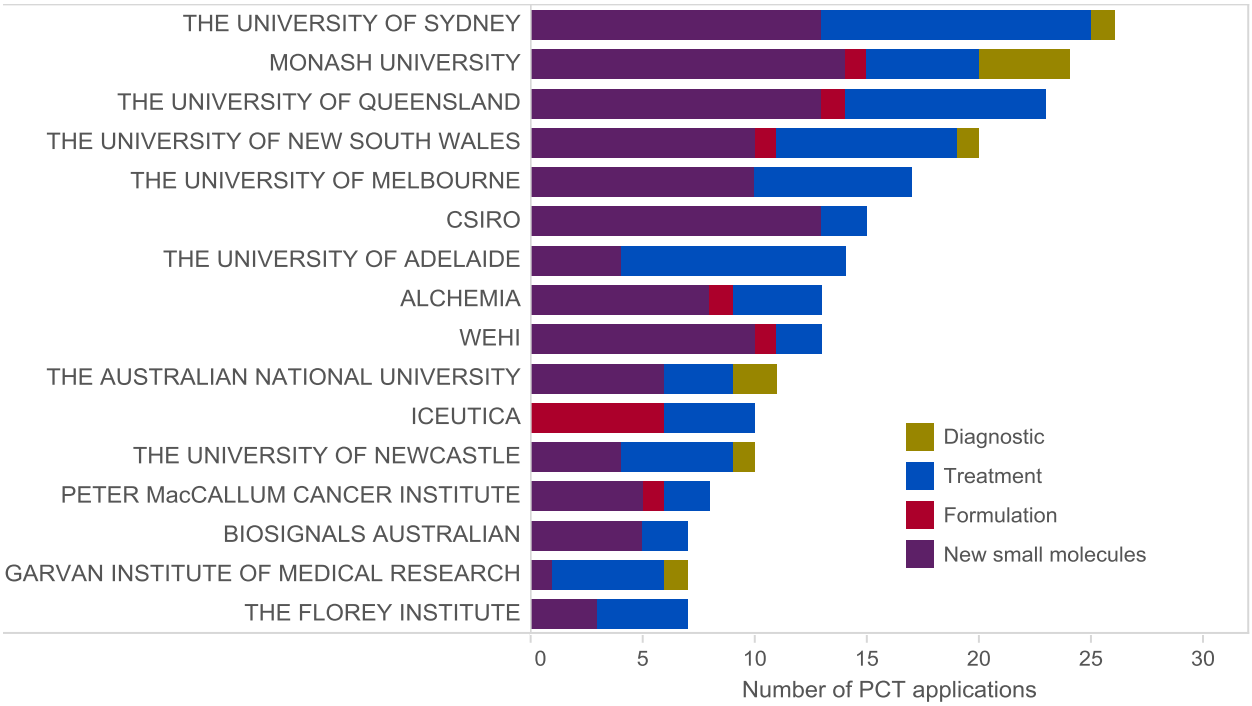


Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; and IP Australia calculations

In contrast to biologics, companies account for 12 of the top 20 PCT applicants in small molecules with only eight coming from research institutes. The University of Sydney, Monash University and The University of Queensland were the top filing research applicants in the small molecules technology category (Figure 15). The University of Sydney, The University of Adelaide and The University of Queensland ranked highest for the treatment subcategory which comprises new methods of treatment using old compounds. Monash University lead the way for filing applications in both the new small molecule category and the diagnostic category. The highest ranked research applicant in the new formulation category was iCeutica, a spin off from University of Western Australia. iCeutica developed SoluMatrix, a drug reformulation technology acquired from the

University of Western Australia. iCeutica was acquired by US based Iroko Pharmaceuticals in 2005.[70]

Figure 15: Top research applicants in small molecules



Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; IPGOD, 2015 edition; and IP Australia calculations

The top companies filing small molecules patents were Biota Scientific Management Pty. Ltd., Bionomics and Vital Health Sciences Pty. Ltd. (Figure 16). Vital Health Sciences Pty. Ltd., founded in Melbourne developed a vitamin E product (Ester-E). Venture Capital firm Vital Capital acquired Vital Health Sciences and struck a deal with Zila Inc. based in the US to license Ester-E.[71] Zila Inc. sold its nutraceutical business in 2006 to NBYT Inc. for approximately $40.5 million.[72]

Vital Health Sciences Pty. Ltd., Advanced Ocular Systems Ltd. and Alphapharm are the highest ranked companies under the treatment category. US based Advanced Ocular Systems Ltd. merged with Perth based company Regenera Ltd.[73] in 2005. In 2009 Advanced Ocular Systems was acquired by International Formwork & Scaffolding Ltd. Advanced Ocular Systems Ltd. was involved with developing and commercialising refractive devices that address vision disorders, and developing pharmaceutical products to treat a variety of eye diseases.[74]

[70] Dean, T 2011, 'iCeutica acquired by US pharma', Life Scientist Australia, 28 April 2011

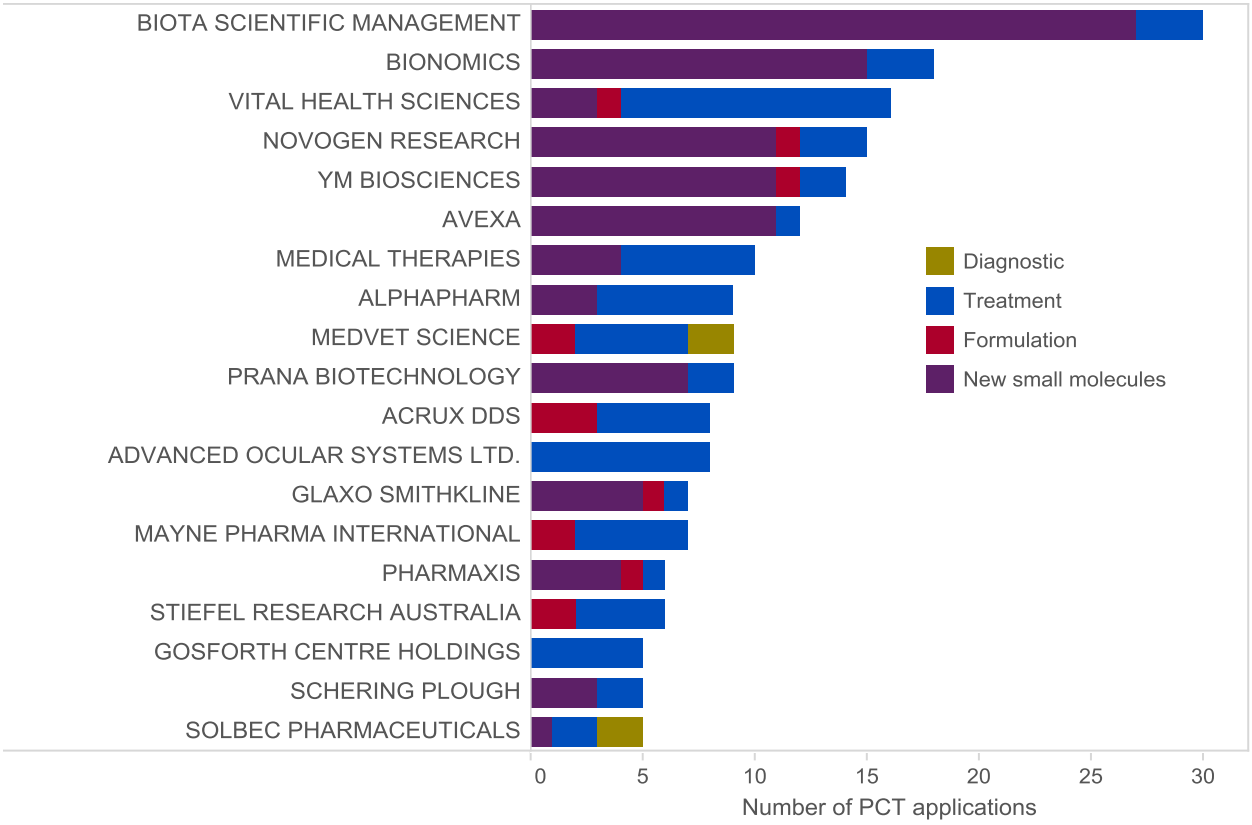
[71] Vital Health Sciences and Zila strike deal for Vitamin E product NPIcentre News, 16 November 2003

[72] Plunkett, JW 2007, 'Plunkett's Biotech & Genetics Industry Almanac 2008: Biotech & Genetics Industry Market Research, Statistics, Trends & Leading Companies' Plukett Research, Ltd., 2007

[73] Business Wire 2005, 'Advanced Ocular Systems, Inc. Announces Proposed Merger with Regenera Ltd; New Global Ophthalmic Company Offers Strong Pipeline of Refractive and Retinal Technology and Products' 31 October 2005

[74] Bloomberg Business, Company Overview of Advanced Ocular Systems Ltd.

Figure 16: Top company applicants in small molecules



Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; IPGOD, 2015 edition; and IP Australia calculations

Biota Scientific Management Pty. Ltd., Bionomics Ltd., Novogen Research (Box 3), YM Biosciences and Avexa were the highest ranked non-research applicants for new compounds. Acrux DDS was the highest ranked non-research applicant for formulation, and Medvet Science Pty. Ltd. and Solbec Pharmaceuticals were equal leading filers for applications in the diagnostic category.

Box 5: Spinifex Pharmaceuticals

The market for pain drugs is expected to be worth over US$3.53 billion by 2022.[75] Spinifex was established in 2005 and conducts preclinical and early-phase clinical studies on new drug candidates for the treatment and management of chronic pain. Spinifex Pharmaceuticals has an office in Melbourne but is headquartered in Stamford, Connecticut.[76] Spinifex's lead candidate, EMA401 has successfully completed a Phase II clinical trial in postherpetic neuralgia (PHN), a neuropathic pain which follows herpes zoster (shingles) in some patients.[77] Spinifex raised an initial AU$3.25 million in Series A funding in 2005/2006 and a total of AU$23.08 million in Series B to support the development of EMA401. In 2014, Spinifex raised a further US$45 million in a Series C round led by Novo Ventures and including additional new investor Canaan Partners. Spinifex has a strong IP portfolio around EMA401, including three applications for in the treatment subcategory of small molecules (WO 2006/066361, WO 2007/106938 and WO 2011/088504),

[75] GlobalData 2014, Neuropathic Pain - Global Drug Forecast and Market Analysis to 2022, p2

[76] Spinifex Pharmaceuticals, About Us

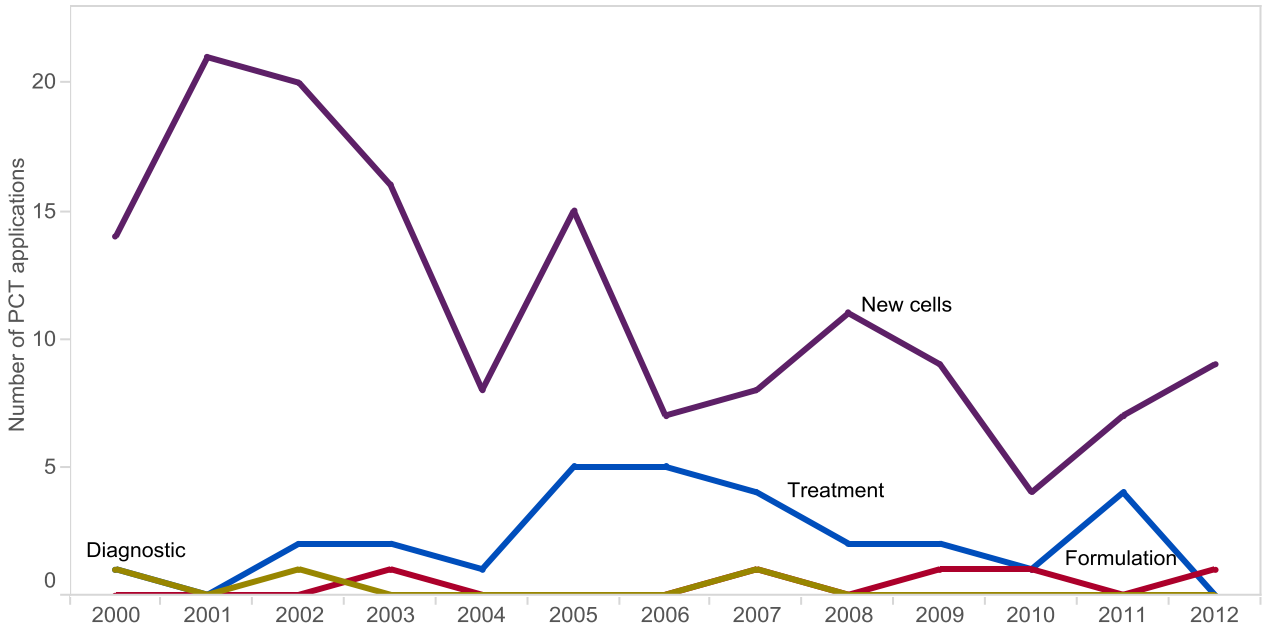
[77] Rice, ASC et al. 2014 'EMA401, an orally administered highly selective angiotensin II type 2 receptor antagonist, as a novel treatment for postherpetic neuralgia: a randomised, double-blind, placebo-controlled phase 2 clinical trial', *The Lancet*, 383(9929), 1637–1647

follow-on candidates and the use of AT2 receptor antagonists to treat both neuropathic and inflammatory pain, including granted patents in the US and Europe.[78] In June 2015 Novartis AG has agreed to buy Spinifex Pharmaceuticals for $200 million upfront with the possibility of Spinifex shareholders getting further payments based on clinical development and regulatory milestones. Novartis plans to start Phase IIb clinical trials in patients with PHN and patients with painful diabetic neuropathy.[79]

5.4 Cells

The category of cells encompasses the use of cells as therapeutics, e.g. stem cells for use in treating disorders. The category does not cover the broader use of cells in tissue engineering, methods of expansion, or other biotechnology applications. We identified 186 applications in this area, which equates to nearly two per cent of all cells applications filed worldwide.

Figure 17: Filing trends—cells



Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; and IP Australia calculations

Cell technologies have also been broken down into the subcategories of new cells, treatment, formulation and diagnostics (Figure 17). Approximately 80 per cent of applications (149) are directed to new cell types with 15 per cent directed to a new therapeutic use or a method of treatment. Formulations and diagnostics make up the remainder. In Australia, applications for new cells peaked in the early 2000s, with an average of approximately 20 applications per year between the years 2000-2003, before declining to an average of approximately 12 applications per year thereafter. During the same period (2000-2012) the world filings were steady. Australian filings in the other categories were sporadic over the period reported on.

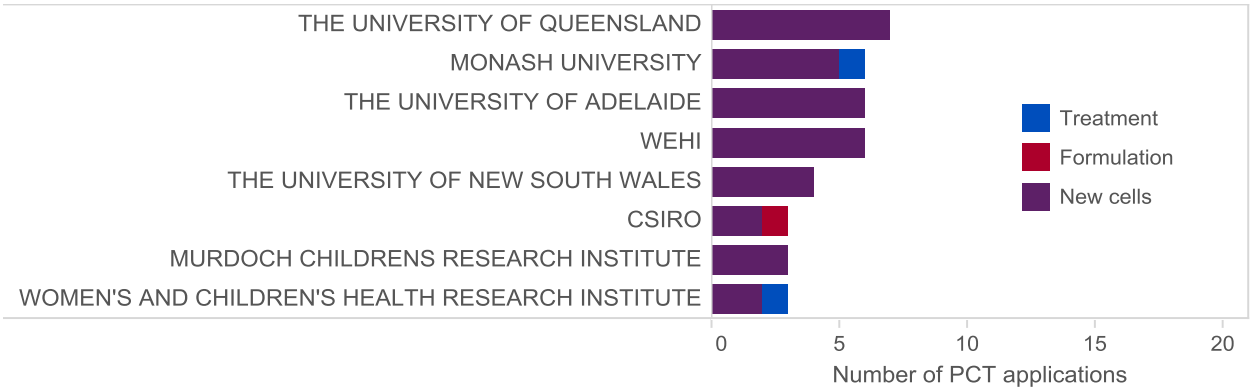
Figure 18 shows the top research applicants. The University of Queensland and the University of Adelaide filed patents on a range of cells, with a particular focus on immunology. Their patents cover antigen-specific cells for suppression of immune responses, precursors for neutrophils and regulatory T-cells, methods of producing haematopoietic progenitor cells that can differentiate into a range of cell such as platelets, monocytes and red blood cells (WO 2009/086596), and

[78] Spinifex Pharmaceuticals, About Us

[79] Reuters, 'Novartis buys pain drug firm Spinifex for $200 million upfront', 29 June 2015

enhancing immune responses though the delivery of cells (WO 2013/170305). Monash has only filed one patent in this area since 2006.

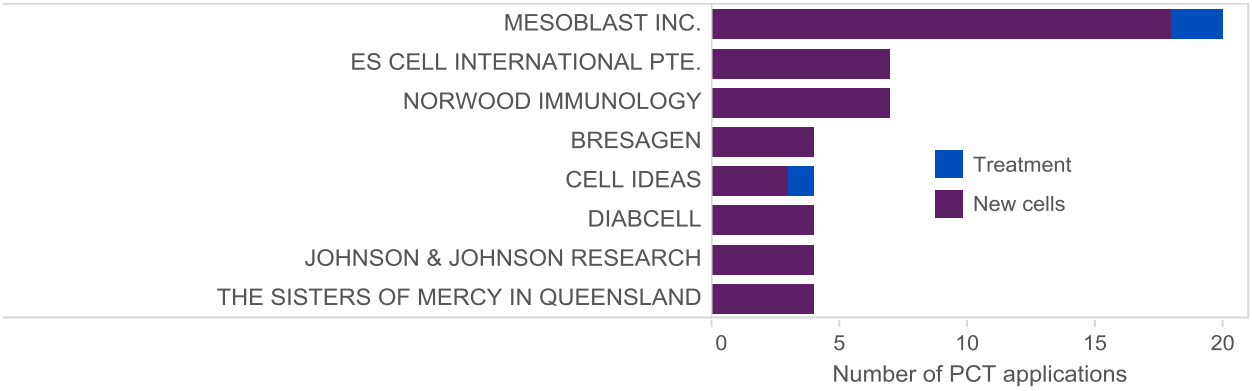
Figure 18: Top research applicants in cells



Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; IPGOD, 2015 edition; and IP Australia calculations

Figure 19 shows the top non-research applicants. Mesoblast, an Australian regenerative medicine company, is the major applicant. Mesoblast is developing biotherapeutics based on its proprietary cell-based and protein technologies.[80] Mesoblast was founded, after acquiring adult stem cell technology from the Hanson Institute and the Institute of Medical and Veterinary Science, both in Adelaide. Mesoblast, who recently had a A$58.5 million investment from Celgene, is expected to be the first company to win approval in the US and Japan for the allogenic adult stem cells.[81]

Figure 19: Top companies applicants in cells



Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; IPGOD, 2015 edition; and IP Australia calculations

ES Cell International Pte. Ltd. (now ESI BIO) is a start-up based on stem cell technology developed by Monash University, the National University in Singapore and Hadassah Medical Organization (Israel). Now headquartered in the US, they have a technology focus on embryonic stem cells.[82]

Cell Ideas Pty. Ltd. is a controlled entity of Regeneus, a Sydney based regenerative medicine company.[83] Similarly, Diabcell Pty. Ltd. is the IP holding subsidiary of Living Cell Technologies. Living Cell Technologies Ltd. is an Australasian cell therapy company focussing on the injection of

[80] Mesoblast, Company Overview

[81] Gardner, J 2015, 'Mesoblast takes partnership with Celgene, shares rise 24pc' Sydney Morning Herald, 13 April 2015

[82] ESI BIO, Our Story

[83] Regeneus, 2014 Annual Report

healthy living cells to replace, repair, or regenerate diseased or damaged tissues.[84] Norwood Immunology and Bresagen are no longer trading.

5.5 Macromolecules

A macromolecule is a single polymeric molecule.[85] For the purposes of this report, the category "macromolecules" includes organic macromolecular compounds such as amino-acid homopolymers, polysaccharides and dendrimers, but doesn't cover peptides, proteins or nucleic acids *per se*.

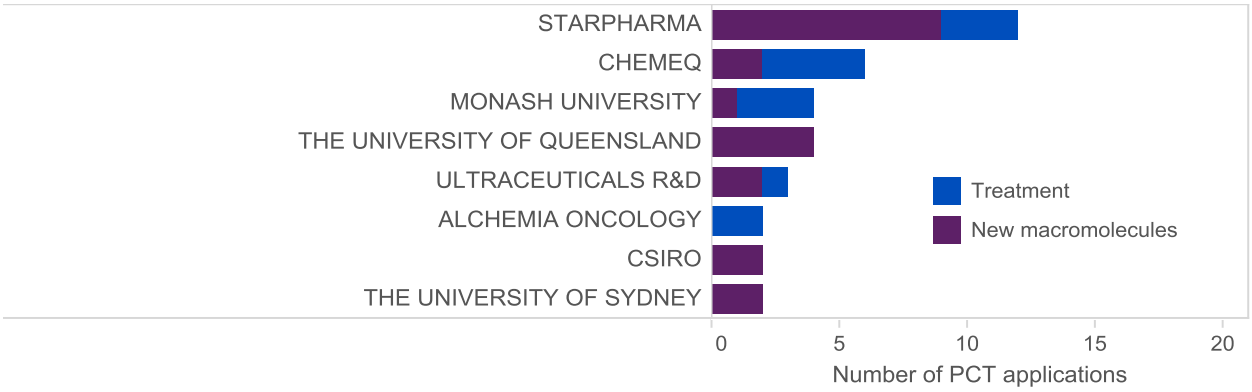
The numbers of pharmaceutical PCT applications falling under the macromolecule category was lower than the other technology categories, so only applicants with more than one application in macromolecules are shown in Figure 20.

Starpharma dominates the field with 12 applications. Starpharma was founded in Melbourne in 1996 and develops dendrimer products for pharmaceutical applications. Starpharma's lead products are based on Vivagel®, a proprietary dendrimer that is formulated as a mucoadhesive delivered vaginally to prevent bacterial vaginosis.[86]

The earliest University of Queensland PCT application in the macromolecules category related to the use of a class of sugars called heparin sulfates and their use in promoting wound and bone repair (WO 2005/107772). This work from the University of Queensland formed the basis of a strong collaboration with the Singapore Agency of Science, Technology & Research (A*STAR).

Chemeq Ltd. was delisted in 2011. They developed anti-microbial polymers for the treatment of diseases as well as for agricultural and industrial use.[87]

Figure 20: Top applicants in macromolecules



Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; IPGOD, 2015 edition; and IP Australia calculations

[84] APBN 2006, 'Living Cell Technologies Granted Diabetes Patent Across the EU', 10(2), 1162

[85] van Holde, KE 1998, *Principles of Physical Biochemistry,* Prentice Hall: New Jersey, ISBN 0-13-720459-0

[86] Starpharma, About us

[87] deListed Australia, Chemeq Ltd.

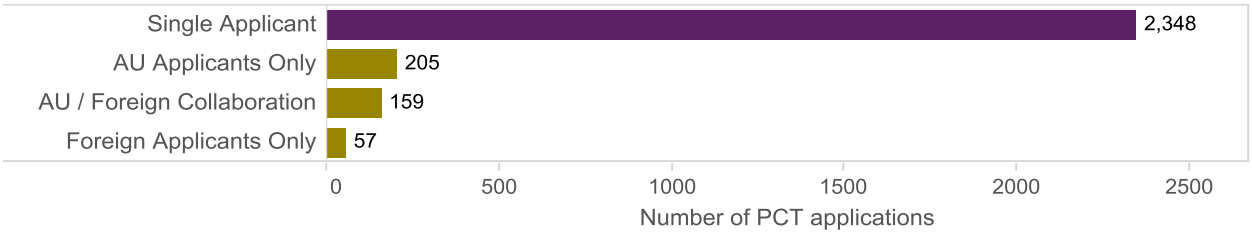
6 Collaboration

One powerful component of the analysis of patent data is the ability to identify research partners collaborating on various inventions. The presence of multiple applicants or multiple inventors on a patent application may be used as a proxy indicator for collaboration.

6.1 Collaboration between applicants

Of the 2768 PCT applications identified only 421 applications (15 per cent) have multiple applicants. A summary of different collaboration modes is shown in Figure 21. Australian applicants were slightly more likely to collaborate with another Australian applicant (205 applications or seven per cent), compared with 159 applications (six per cent) that contained a foreign co-applicant. There were 57 applications (two per cent) that contained only foreign co-applicants. These applications appear in the data set as they contain an Australian inventor working for a foreign entity.

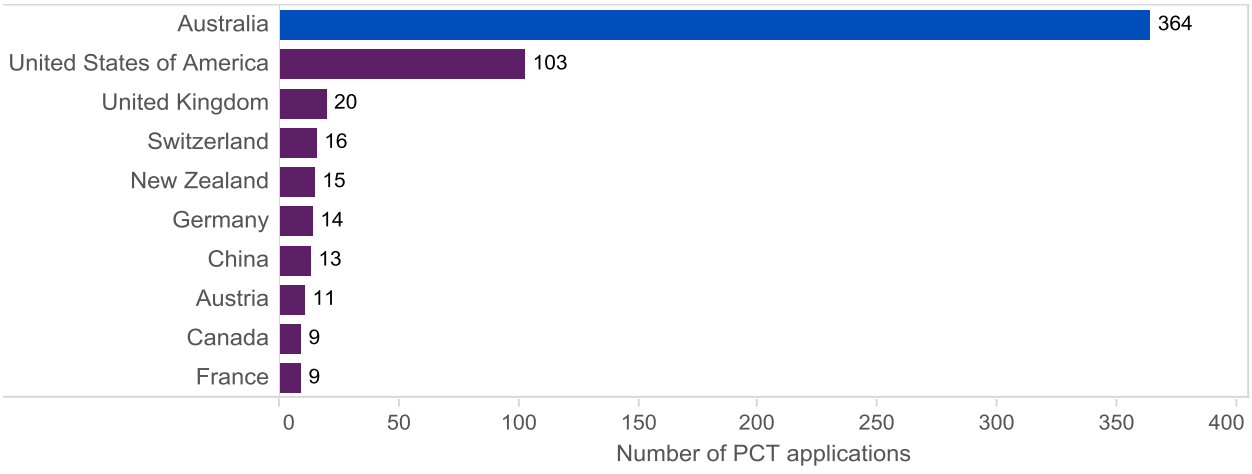
Figure 21: Applicant collaboration modes.



Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; and IP Australia calculations

Countries collaborating with Australia in the pharmaceutical industry can be measured by identifying Australian PCT applications listing more than one applicant, and examining the country of origin of the other co-applicants. This distribution is shown in Figure 22. Applicants from the US are the preferred partners, followed by the UK, Switzerland and New Zealand.

Figure 22: International collaboration with Australian applicants.



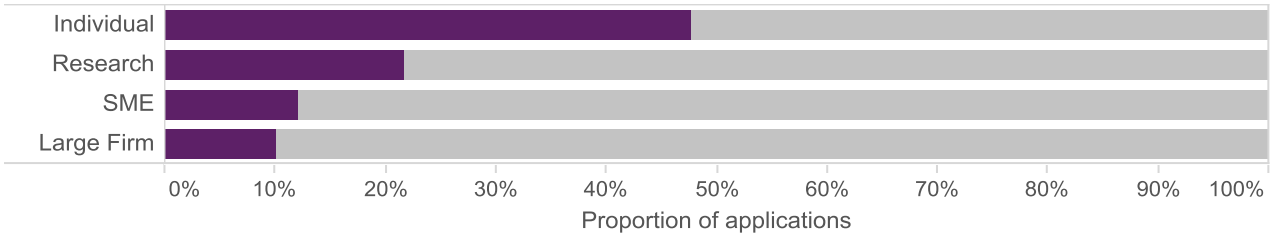
Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; and IP Australia calculations

6.2 Collaboration between applicant types

An investigation into the likelihood of different applicants, or entity types, collaborating on their applications is shown below in Figure 23. Figure 23 demonstrates the proportion of applications where Australian entities have collaborated. Research entities collaborated on 22 per cent of

applications, followed by SMEs (12 per cent). Large firms are the least likely to collaborate on applications in this area with only 10 per cent of applications filed with more than one applicant.

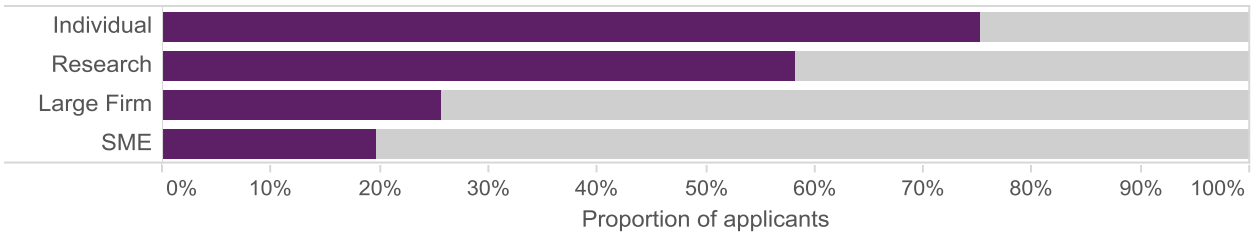
Figure 23: Proportion of applications assigned to entity types where collaboration is evident



Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; IPGOD, 2015 edition; and IP Australia calculations

Figure 24 shows the proportion of applicants who collaborate. Almost 60 per cent of research entities have at least one patent with a co-applicant. This is much greater number than both large firms and SMEs. Approximately 80 per cent of SMEs included in the study have not filed any patents with a co-applicant. Both figures show that individuals are more likely to collaborate. A large portion of these are likely to be applicant/inventors who had not assigned their rights to a parent organisation, and probably do not represent true collaboration. It should be noted that this is only a measure of a specific type of collaboration, other forms of knowledge transfer and links between entities are not represented, and hence this likely underestimates the total interactions that occur between entity types.

Figure 24: Proportion of applicants who collaborate, by entity type



Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; IPGOD, 2015 edition; and IP Australia calculations

Table 3 shows the number of applications that result from collaborations between the research sector and industry in Australia. Out of 364 applications (in Figure 22) with at least one Australian applicant, 182 had more than one Australian applicant (not including individuals). Out of these, 167 applications had an applicant from the research sector (Table 3) and 38 per cent of those applications had industry-research collaboration.

Table 3: Collaborations between Industry and Research sectors

Number of PCT applications	Research	SME	Large Firm
Research	104	47	16
SME		5	2
Large Firm			8

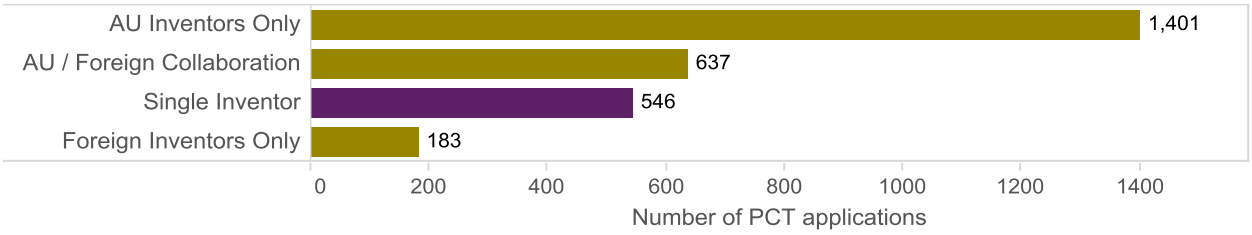
Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; IPGOD, 2015 edition; and IP Australia calculations

6.3 Collaboration between inventors

Different collaboration modes identified by inventor origin is shown in Figure 25. Approximately 30 per cent of PCT applications (820) contain foreign inventors. This was split between 637

applications (23 per cent of the total) that had an Australian and a foreign inventor and applications that had only foreign inventors, but an Australian applicant (7 per cent).

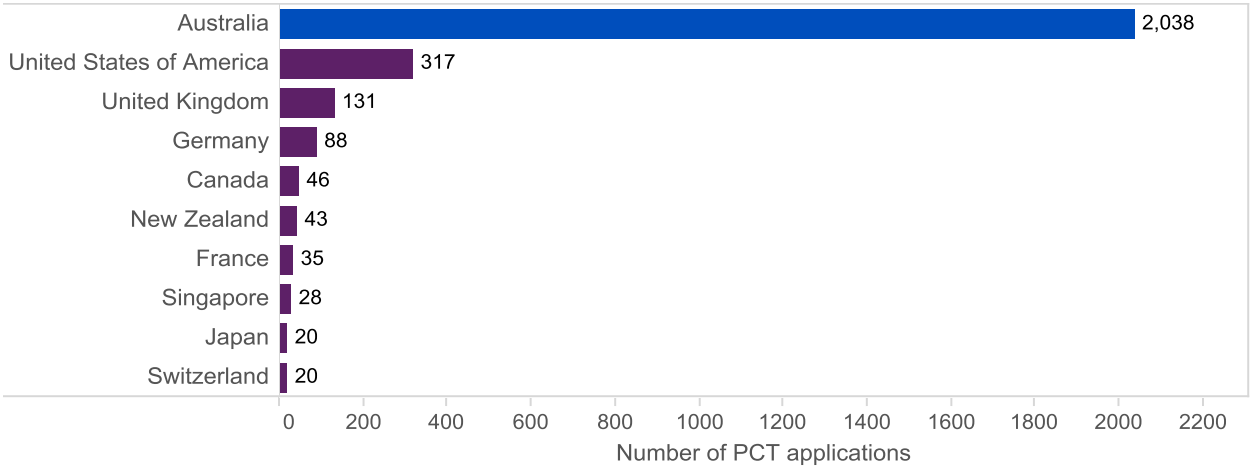
Figure 25: Inventor collaboration modes.



Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; and IP Australia calculations

Analysis identifying the country of origin of co-inventors is shown in Figure 26. Similar to the applicant data, the top countries Australians collaborated with by inventor were the US and the UK.

Figure 26: Number of inventors by country



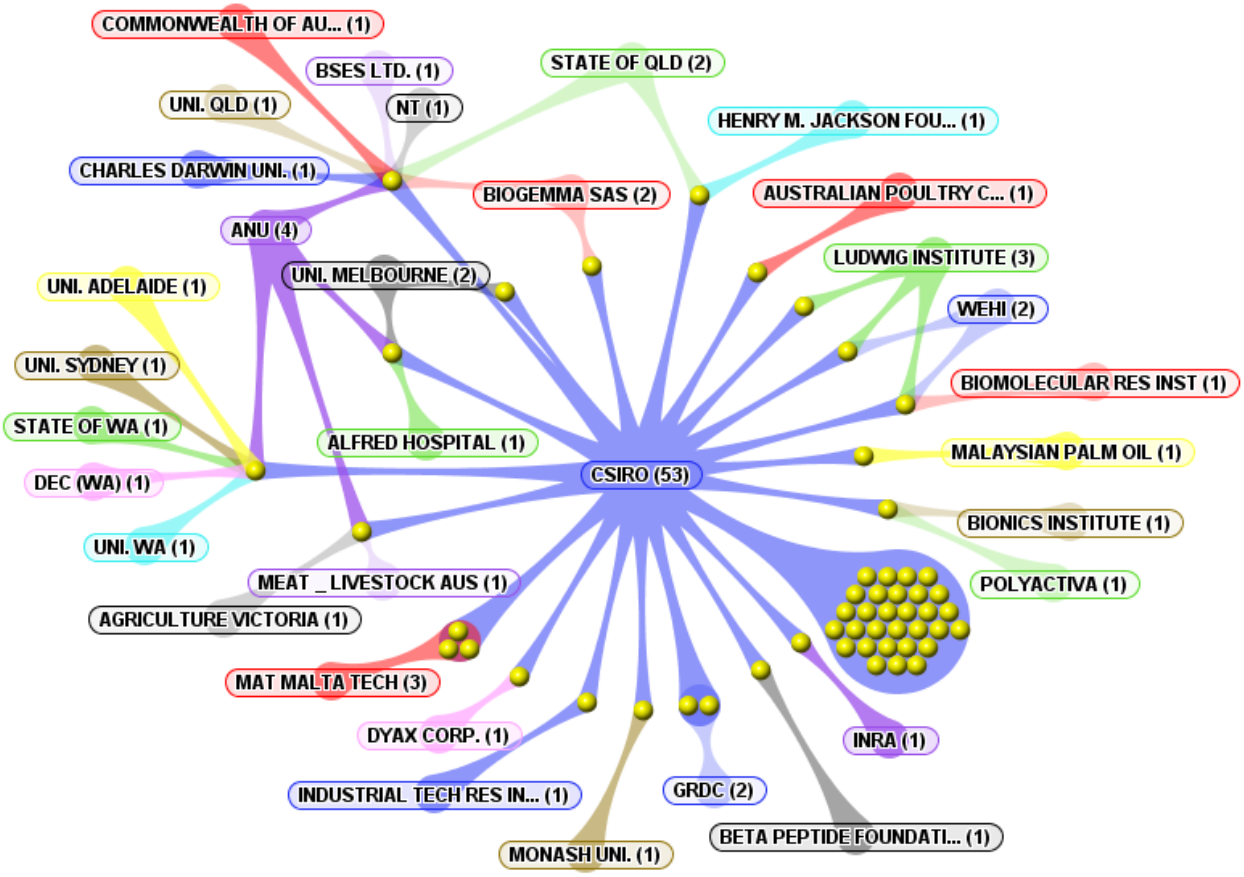
Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; and IP Australia calculations

6.4 Collaborative work by publicly funded entities

A detailed analysis of collaborations between publicly funded entities and other similar organisations or firms, provides a more detailed picture of the partnerships that exist, via their filing patterns with co-applicants. The collaboration maps used in the following sections demonstrate both the portfolio of the entity of interest, shown as collection of nodes located centrally next to the entity name, and also shared assets as a web branching out from the central entity. In this way we can graphically demonstrate any relationships that exist between these entities.

CSIRO is one of the largest filers of patents in Australia and prides itself on collaborating with as many research partners as possible.[88] Its collaborations within the pharmaceutical space are shown in Figure 27. As CSIRO advertises in its annual report, it files broadly with others, rather than exclusively on its own, and there is no specific partner identified in our analysis. The Walter and Eliza Hall Research Institute, Ludwig Institute, and the University of Melbourne are examples of research entities with which CSIRO has filed multiple patents in the pharmaceutical industry.

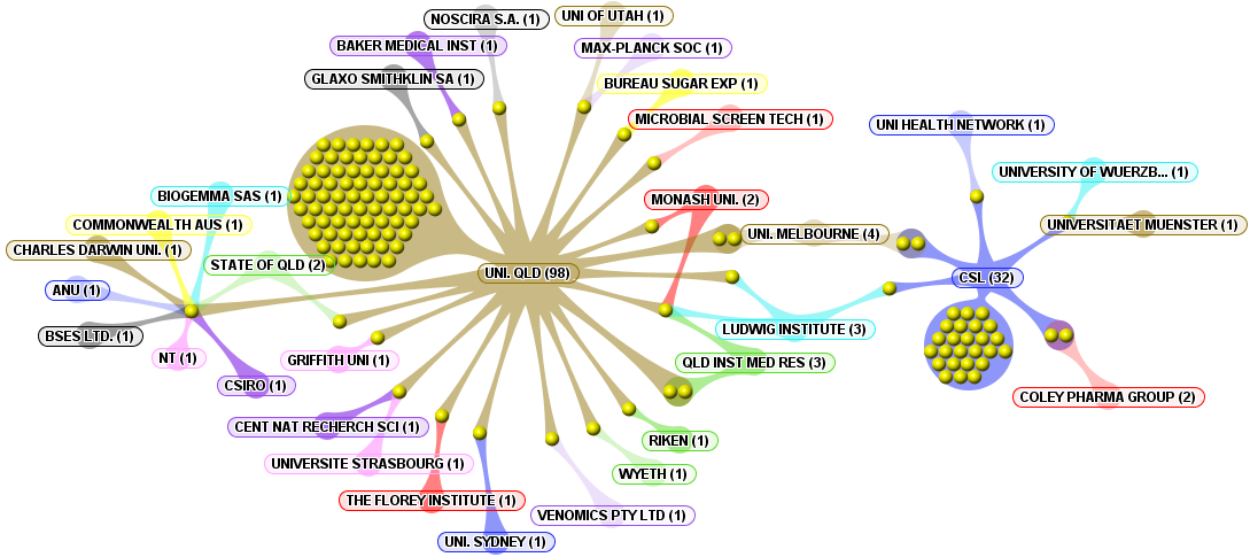
Figure 27: Patent collaborations with the CSIRO



Along with the CSIRO, the University of Queensland (UQ) is one of the top pharmaceutical applicants and its collaborations are shown in Figure 28. Although a majority of its applications are filed on its own, UQ files with a wide variety of applicants including foreign universities, local universities, firms and even local governments. Of particular importance are the Queensland Institute of Medical Research (QIMR) and the Ludwig Institute for Cancer Research. CSL is connected to UQ via both the University of Melbourne and also the Ludwig Institute. Further analysis into research partners of the Ludwig Institute of Cancer Research and CSL is shown in Figure 31 and Figure 33, respectively.

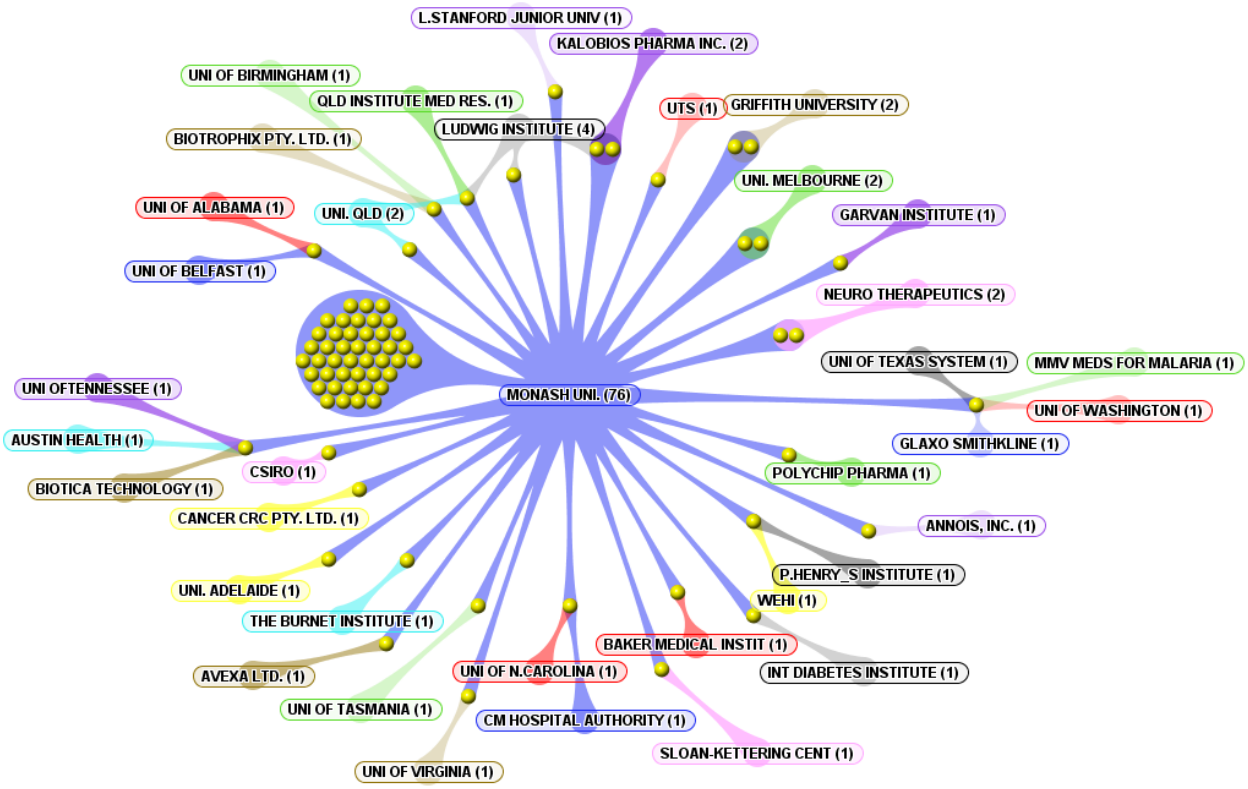
[88] CSIRO, '[Collaboration, connections and advice]' Annual Report 2011-12

Figure 28: Patent collaborations with the University of Queensland.



Monash University was also identified in our analysis as one of the largest collaborators, and its interactions are shown in Figure 29. Monash University has an extensive network of collaborators, even more so than the CSIRO. Monash has a number of multi-applicant collaborations with the Ludwig Institute for Cancer Research (see also Figure 31). Monash University has also collaborated with eight foreign universities, comprising Leland Stanford Junior University, University of Birmingham, University of Alabama, University of Belfast, University of Tennessee, University of Northern Carolina, University of Washington and University of Texas System. This can be compared to the list of local universities of which there are only six.

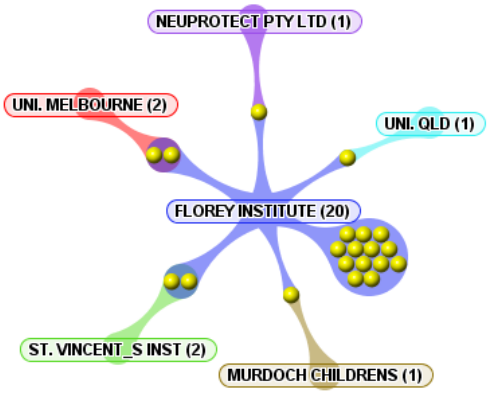
Figure 29: Patent collaborations with Monash University



6.5 Collaborations by research institutes

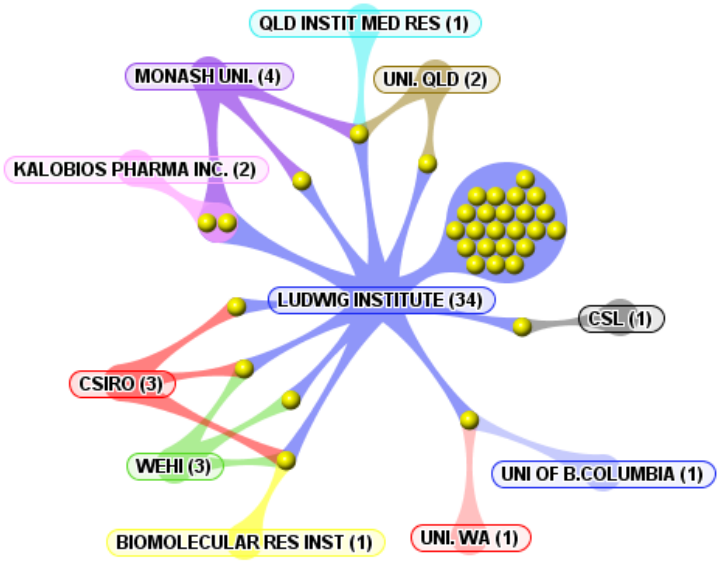
Although WEHI is the top research institute in terms of total applications, they only collaborated on six applications. The top collaborating research institutes are the Florey Institute and the Ludwig Institute for Cancer Research. Their collaborations are shown below in Figure 30 and Figure 31, respectively. Approximately one third of the Florey Institute's applications are filed in collaboration with other institutions, only one of which is a company (Neuroprotect Pty. Ltd.).

Figure 30: Patent collaborations by the Florey Institute



The Ludwig Institute's collaboration map, shown in Figure 31, demonstrates the most interconnected network of those discussed in this report, with approximately one third of their applications including a co-applicant. Not only does the Ludwig Institute collaborate with other research institutions, but these co-applicants are also collaborating on different projects with each other. These include Monash University, WEHI and the CSIRO.

Figure 31: Patent collaborations by the Ludwig Institute



6.6 Collaborations with SMEs

Almost no evidence of collaborations from SMEs is evident in our analysis of applicant collaborations.

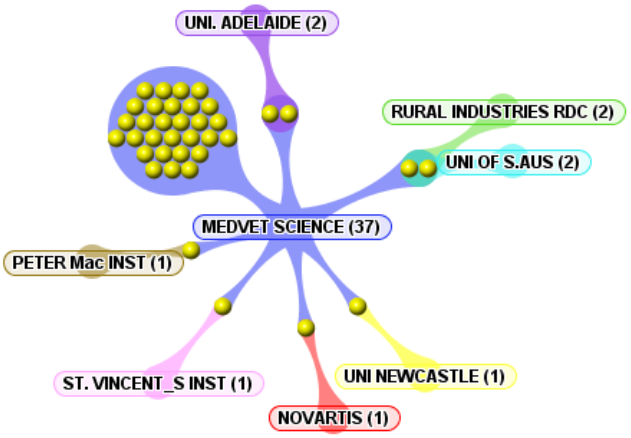
This is not surprising considering there is a trend towards integration of biopharmaceutical companies beyond arm's-length licensing. Vertical integration is often characterised by a biotechnology company expanding to downstream development, or a pharmaceutical company expanding to upstream research. Horizontal integration is characterised by merger and acquisition activity. [89] The result of such integration is limited collaboration activity between companies in relation to patenting.

As such, small companies in this industry are more likely to look short term to make themselves attractive to bigger firms as a possible future asset. Globally, large pharmaceutical companies are moving to largely outsourced models for R&D relying on publicly funded organisations and small biotech companies to support their drug pipelines.

The only reasonable example of an SME with significant collaborative links in our dataset is Medvet Science, which was formally a technology transfer company of the Institute for Medical & Veterinary Science (IMVS)[90] and is now a private company whose only shareholder is a division of the South Australian government. As such, Medvet Science is not a typical small start-up. Its collaborations are demonstrated in Figure 32. While Medvet Science has predominantly collaborated with two South Australian universities (University of Adelaide and the University of South Australia), Medvet Science has also collaborated with other research institutes, a university and the large company Novartis.

The Novartis collaboration involved the research of Professor Deborah White (formerly the Scientific Head of Haematology research at SA Pathology).[91] Professor White in collaboration with Novartis, has been granted a patent in the US disclosing a method of treating chronic myeloid leukaemia (US 8697702).

Figure 32: Patent collaborations by Medvet Science



6.7 Collaborations in industry

Like SME collaboration, the applicant share analysis presented here provides little evidence of collaboration in industry. CSL was the largest industry collaborator (Figure 33). CSL collaborated

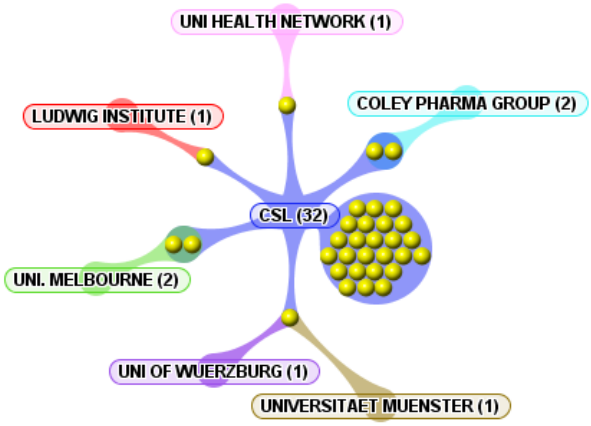
[89] Rai, AK 2001, 'Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust', *Berkeley Technology Law Journal*, 2000, 16, 813-853 (at 816-818)

[90] TransBio, Governance and Management

[91] South Australian Health and Medical Research Institute, Professor Deb White

with the Coley Pharma Group, the University of Melbourne as well as some overseas universities. Coley Pharma Group develops therapeutics cancer, allergy, asthma and autoimmune disorders and was acquired by Pfizer in 2007.[92]

Figure 33: Patent collaborations by CSL



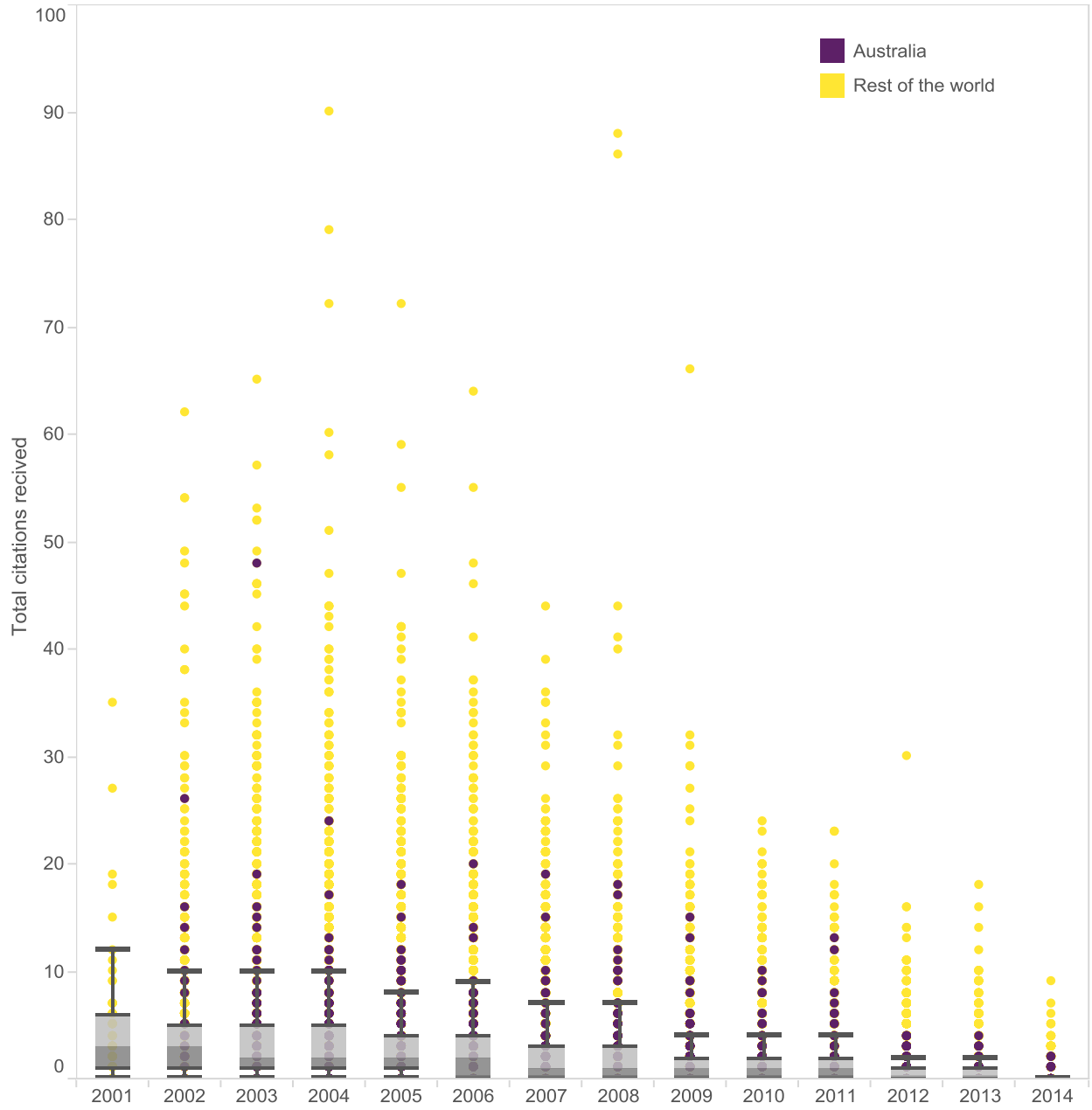
[92] Pfizer Press Release 2007, 'Pfizer to Acquire Coley Pharmaceutical Group', 16 November 2007

7 Citation analysis

Citation analysis is a useful tool to provide an indication of how new or inventive a particular invention is. During the examination process, citations or documents of particular relevant to the current invention are raised by patent examiners. Figure 34 represents the combined citations a patent received from international (PCT) and European search and examinations reports. It shows the number of citations for a patent application when compared against other patents published in the same year.

This provides a measure of the 'importance' of an invention disclosed within an application. This is then broken down into those applications originating from Australia versus the rest of the world. The higher the number of times an application is cited, the greater the weight of impact it has in the field. As can be seen in Figure 34, Australia has had a good track record of producing inventions that have an above-average impact over the years.

Figure 34: Forward citations received by pharmaceutical PCT applications worldwide.



Source: PATSTAT database, Autumn 2014; OECD, REGPAT database, February 2015; OECD, Citations database, February 2015; and IP Australia calculations

The following sections highlight some of the Australian applications that have a large number of citations compared to their publication year cohort.

7.1 Cytopia

The most highly cited Australian pharmaceutical PCT application was WO 2002/060492 by Cytopia Pty. Ltd. It has 48 citations, whilst the median number of citations for applications published in 2003 was 3 (based on the publication date of the European application), with the upper whisker representing a standard deviation of 10 citations.

This application discloses a Janus kinase (JAK) inhibitor compound and a method of inhibiting JAK in a cell. Cytopia's lead compound, CYT997 underwent Phase II clinical trials for use as a cancer treatment. Cytopia Pty. Ltd. merged with Canadian based YM Biosciences Inc. in 2010. YM Biosciences was bought by Gilead Sciences Inc., the world's biggest maker of AIDS drugs, for US$510 million in 2012 to advance YM Biosciences lead drug candidate CYT387, a JAK1/JAK2 small molecule inhibitor targeting the treatment of myelofibrosis, a bone marrow disease that can lead to anaemia and an enlarged spleen. The JAK inhibitor momelotinib has progressed to Phase III clinical trials.[93]

7.2 Thrombogenix

The second most cited Australian pharmaceutical PCT application is WO 2001/053266 from Thrombogenix Pty. Ltd., with 26 citations. This application discloses compounds having anti-thrombotic activity and resultant national phase entries have been granted in the US and Europe.

Thrombogenix was established by Monash University, changed its name to Kinacia Pty. Ltd. and was acquired in 2004 by Cerylid Biosciences Ltd.[94] Kinacia's lead compound, KN309, was shown in animal studies to inhibit blood clot formation without causing bleeding.[95] Cerylid's lead compound CBL316 is an antithrombotic compound that specifically targets pathological thrombus formation under conditions of rapid blood flow/high shear stress.[94] Cerylid planned to begin phase 2 trials in 2006.[96] Cerylid appears to have since wound up with its IP relating to anti-thrombotic compounds having been assigned to AstraZeneca.

7.3 Savine Therapeutics

Another highly cited Australian pharmaceutical PCT application was WO 2001/090197 from the Australian National University (ANU), with 19 citations. This application discloses synthetic polypeptides and polynucleotides encoding them and their use in immunopotentiating compositions. The application was granted in the US (US 7820786 B2) in the name of Savine Therapeutics Pty. Ltd., which was created to commercialise the technology from the ANU. The US patent claims methods for inducing immune responses against HIV using synthetic polypeptides comprising at least three different segments of an HIV polypeptide. Savine Therapeutics was founded in 2007 to commercialise Scrambled Antigen Vaccine (Savine) intellectual property. BioDiem, a Melbourne based vaccine developer, acquired Savine Therapeutics in 2011.[97] BioDiem is currently seeking a licensing or co-development partner for the Savine technology.[98]

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[93] Gilead, Research Pipeline

[94] Bloomberg Business, 'Company Overview of Kinacia Pty Ltd.', 30 July 2015

[95] Australian Life Scientist, 'Cerylid, Kinacia to merge', 2 June 2004

[96] Australian Life Scientist, 'Cerylid to test new clot-prevention drug', 18 April 2005

[97] Australian Life Scientists, 'BioDiem buys Savine Therapeutics', 15 December 2011

[98] BioDiem, Licensing Strategy and Available Licenses, 30 July 2015

7.4 University of Western Australia

PCT application WO 2006/000057 from the University of Western Australia was another highly cited pharmaceutical application, with 19 citations. This application discloses an antisense molecule capable of binding to a selected target site to induce exon skipping in the dystrophin gene, and its use in treating muscular dystrophy. The application has proceeded to grant in both the US and Europe. The inventor, Steve Wilton was awarded more than US$400,000 over three years from the Muscular Dystrophy Association of the US to further improve Duchenne Muscular Dystrophy (DMD) treatment. Professor Wilton has called the antisense oligonucleotides of the invention "genetic band-aids" as he uses them to trick the body's gene transcription machinery to "skip over" the flawed parts of the dystrophin pre-mRNA that lead to DMD.[99]

[99] University of Western Australia 2010, 'US body backs UWA researcher's muscular dystrophy research' University News, 2 September 2010

8 Conclusion

Our search identified 2768 Australian pharmaceutical PCT applications, which accounts for 10 per cent of all Australian PCT applications between 2000 and 2012. This comparable to other technologies such as medical devices and civil engineering, and shows the emphasis that Australian innovators place on pharmaceutical technology.

On a world scale, Australia has 1.5 per cent of pharmaceutical patents over the study period which places it 13th based on inventor share, just behind Israel and Switzerland. Australia also has a positive specialisation in the pharmaceutical technology, which reinforces the strength that Australia has in the area.

Australia has a slight focus on biologics (43 per cent of applications) when compared with small molecules (37 per cent). This is in contrast with the rest of the world during the same period, in which small molecules make up 49 per cent of applications compared with just 29 per cent for biologics. This indicates that Australia has a particular strength on the development of biological therapeutics.

Within Australia, the majority of inventions originate in Victoria. The top destinations for pursuing patents are the US, Australia, Europe, China and Japan.

Research organisations dominate the patenting landscape, filing 40 per cent of applications, followed by SMEs (21 per cent) and foreign corporations (19 per cent). A large number of SMEs with significant patent portfolios had their origins in research organisations. This trend is the same for both PCT applications and national phase entries in Australia. Out of the top 21 applicants, 16 are research organisations and only five are companies. The top applicants are the University of Queensland, Monash University and WEHI. Top companies are Bionomics, Biota, CSL and Mesoblast. Significant numbers of SMEs owe their establishment to research organisations, demonstrating how much these organisations drive the Australian pharmaceutical industry. Australian generic manufacturers also file patents, and contribute not just to Australia, but are part of a global industry.

There is not a strong collaborative link between Australian industry and research organisations. Out of 167 applications with an applicant from the research sector, 38 per cent of had industry-research collaboration. Top patent filers such as the University of Queensland, Monash University and the CSIRO have extensive links and they collaborate with overseas entities as well as Australian partners. SMEs show very little evidence of collaboration. Large Australian pharmaceutical firm CSL does not show many collaborative patent links either.

There are many cases of success stories from the Australian pharmaceutical industry, whether it is new drugs or therapeutic approaches, generic exports, or start-up companies based on publically funded research being bought by large overseas companies who found value in the technology.

Appendix A: Search methodology

The identification of patents with pharmaceuticals was done in two phases:

Phase 1: PATSTAT search

The study drew on patent data from:

- AusPat: Australian patent database administered by IP Australia;
- IPGOD: Australian Intellectual Property Government Open Data;
- Worldwide patent statistical database (PATSTAT), Autumn 2014 edition, developed by the EPO, covering data from over 100 countries; and
- OECD REGPAT database, July 2014 edition, developed by the OECD and derived from the PATSTAT and EPOline databases.

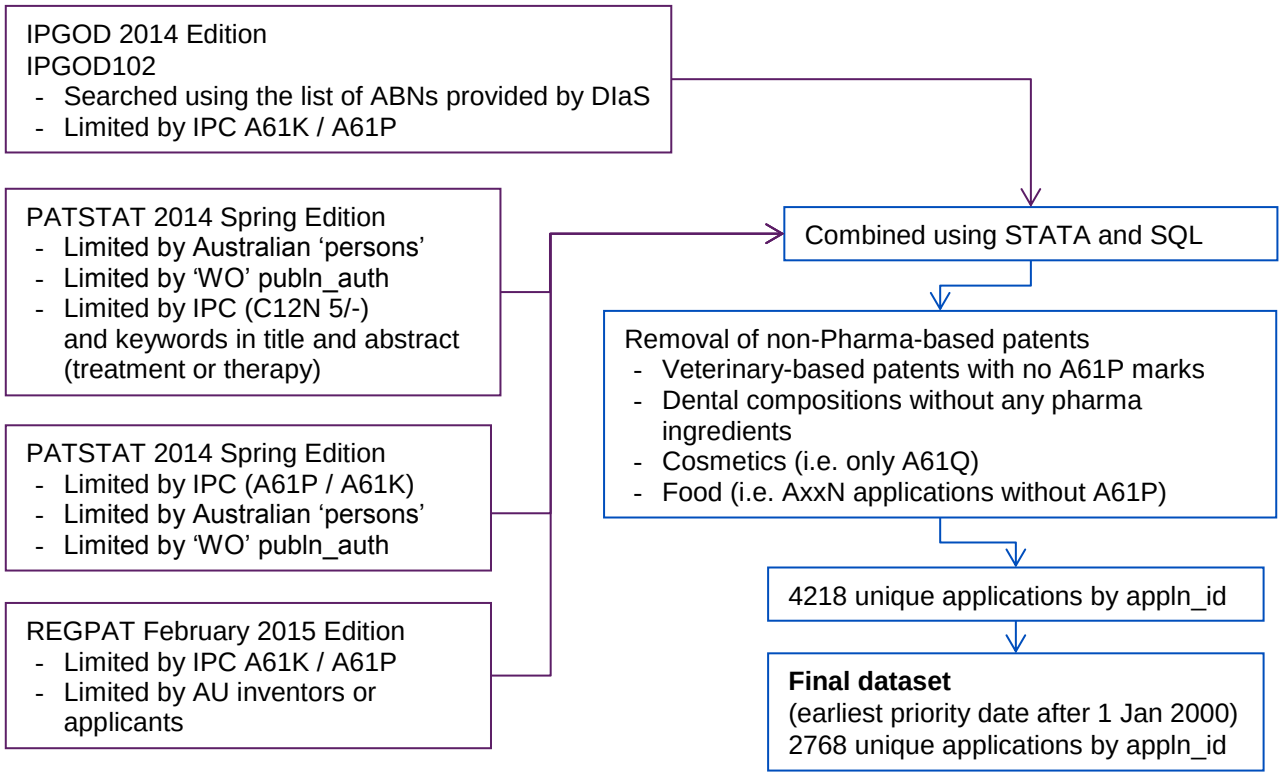
The Autumn 2014 edition of the PATSTAT database used to identify PCT applications in this study contains all publications to the beginning of September 2014, essentially comprising publications with a priority date up to March 2013. Some documents with later priority dates are published less than 18 months from the priority date and are in the database.

The patent search encompasses Australian-originating PCT applications. PCT applications pertaining to pharmaceuticals and biopharmaceuticals will commonly be indexed with a classification mark associated with the active pharmaceutical ingredients (e.g. C07D and C07C for organic molecules; and C07K and C12N for biomolecules), a classification mark associated with the pharmaceutical compositions containing the active pharmaceutical ingredient (e.g. A61K) and a classification mark associated with the disclosed therapeutic use (A61P) (see Figure 35). Patents were considered to fall within the pharmaceutical technology category if they had an A61K or A61P IPC mark. Patent applications which only contain classification marks associated with the compounds or biomolecules *per se* (i.e. C07K alone) were not considered as they do not have a 'pharmaceutical' use. For a detailed description of IPC marks see Appendix B.

Cells used as therapeutics were also included. Some of these patents were already in the set via the A61K/A61P search. For a more complete picture of the therapeutic use of cells we added patents with C12N 5/- marks and having the keywords (treatment or therapy) in title or abstract. It should be noted that this is a subset of patents pertaining to cells, and does not represent the entirety of Australian cellular research. Keywords were used to help define this subset.

The first phase of the search was to identify the patent applications relevant to the pharmaceutical industry filed via the Patent Cooperation Treaty (PCT) route with a priority date between 2000 and 2013. Phase one of the search identified 2768 unique applications from the PATSTAT database.

Figure 35: Search strategy



Phase 2: IPGOD—Patents

Australian national-phase entry (NPE) and firm data were extracted from the Intellectual Property Government Open Data (IPGOD) published by IP Australia.[100] The IPGOD includes over 100 years of IP rights administered by IP Australia comprising patents, trade marks, designs and plant breeder's rights. The data is highly detailed, including information on each aspect of the application process, from application through to granting of IP rights. An important feature of the IPGOD is the ability to match IP administrative data with firm-level business characteristics for Australian companies.

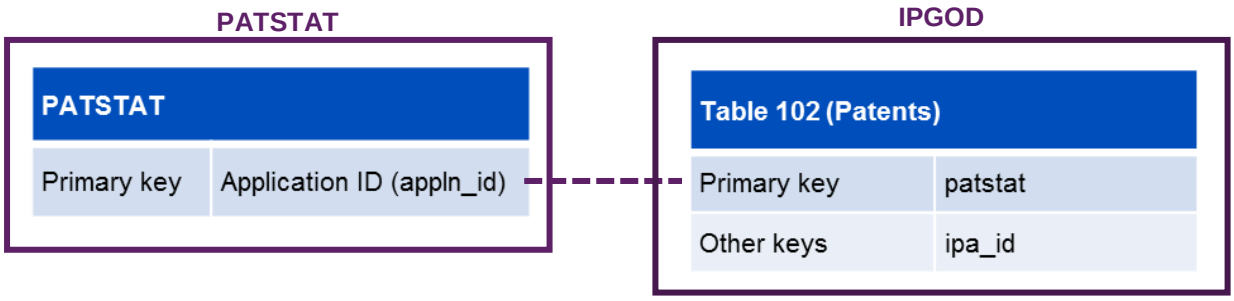
The IPGOD includes geospatial data such as the state/territory and postcode of the applicant, and a geocode of the applicant address, as well as a marker indicating the quality of the geocoding. We used this data to identify the origin of Australian pharmaceutical patents.

The IPGOD only contains bibliographic information on patent applications filed in Australia between 1990 and 2014 obtained from IP Australia databases. Therefore the match firm level IPGOD tables contain a record for those PCT applications which have entered national phase in Australia as of 31 December 2014 and are open for public inspection.

A schematic showing the link between the PATSTAT and the IPGOD database is shown in Figure 36.

[100] Man, B 2014, 'Overview of the Intellectual Property Government Open Data'. IP Australia Economic Research Paper 02; Julius, TD & Rassenfosse, G 2014, 'Harmonising and Matching IPR Holders at IP Australia' Melbourne Institute Working Paper Series Working Paper No. 15/14

Figure 36: Data schema between the PATSTAT and the IPGOD.



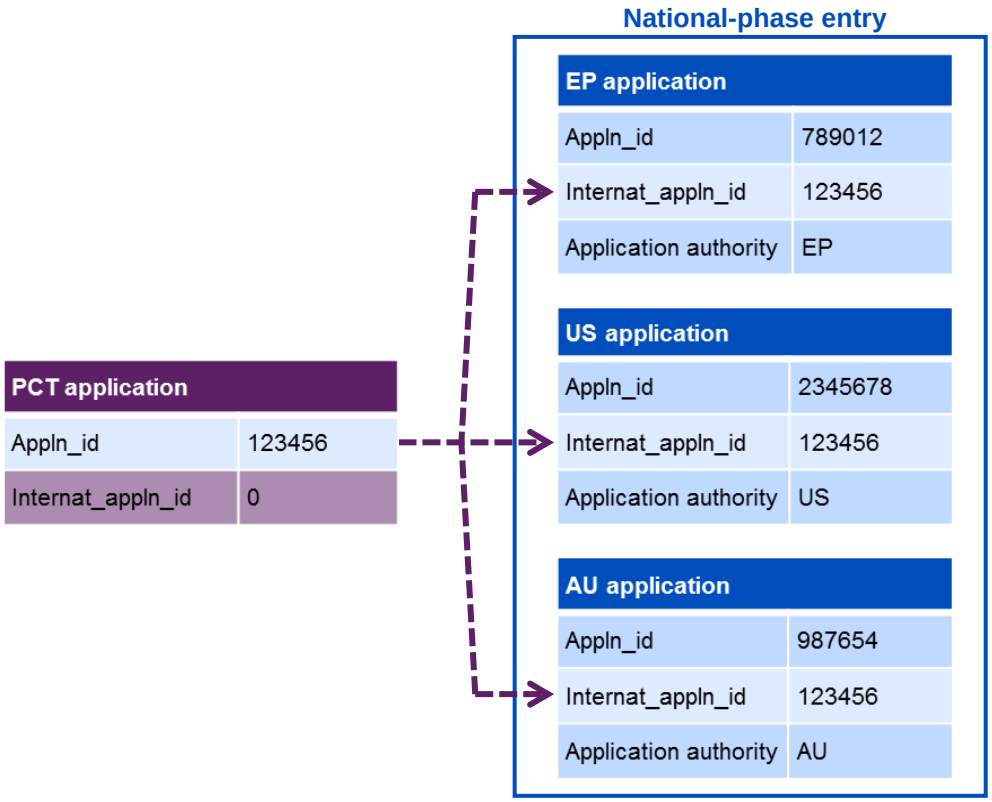
The NPEs for PCT applications can be identified in PATSTAT by cross-referencing the 'appln_id' against 'internat_appln_id' in the PATSTAT database. A schematic showing the link between the PCT applications and their corresponding NPE applications are shown in Figure 37.

Australian NPE applications are identified by selecting applications with the value 'AU' in the 'appln_auth' field in the PATSTAT database.

Based on the 2768 unique applications identified in the first phase of the search, a total of 1657 Australian NPE applications were found.

Using a combination of either 'appln_id' or 'appln_nr' from PATSTAT the bibliographic and firm-level information of the Australian NPE applications were retrieved from IPGOD table 102 containing only Australian-based applicants.

Figure 37: Relationship between a PCT application and corresponding national-phase entries.



Appendix B: Description of IPC Marks

Subclass	Maingroup	Description
A61K		Drug or other biological compositions (mixtures) which are capable of preventing, alleviating, treating or curing abnormal or pathological conditions of the living body
	31	Medicinal preparations containing organic active ingredients
	35	Medicinal preparations containing materials in indeterminate constitution: materials from mammals, other animals, bacteria etc.
	38	Medicinal preparations containing peptides
	39	Medicinal preparations containing antibodies or antigens
A61P		Specific therapeutic activity of chemical or biological compounds or medicinal preparations already classified elsewhere
A61Q		Specific use of cosmetics or similar toilet preparations
C07C		Acyclic or carbocyclic compounds
C07D		Heterocyclic compounds
C07F		Acyclic, carbocyclic, or heterocyclic compounds containing elements other than carbon, hydrogen, halogen, oxygen, nitrogen, sulfur, selenium or tellurium
C07H		Sugars; derivatives thereof; nucleosides; nucleotides; nucleic acids
	21	Compounds containing two or more mononucleotide units having separate phosphate or polyphosphate groups linked by saccharide radicals of nucleoside groups, e.g. nucleic acids
C07J		Steroids
C07K		Peptides
C08*		Organic macromolecular compounds; their preparation or chemical working-up; compositions based thereon
C12N		Micro-organisms or enzymes; compositions thereof; propagating, preserving, or maintaining micro-organisms; mutation or genetic engineering
	5	Undifferentiated human, animal or plant cells
C12Q		Measuring or testing processes involving enzymes or micro-organisms
G01N		Investigating or analysing materials by determining their chemical or physical properties

Appendix C: Technology Breakdown

Figure 38: Flowchart of the technology sorting used to create the categories.