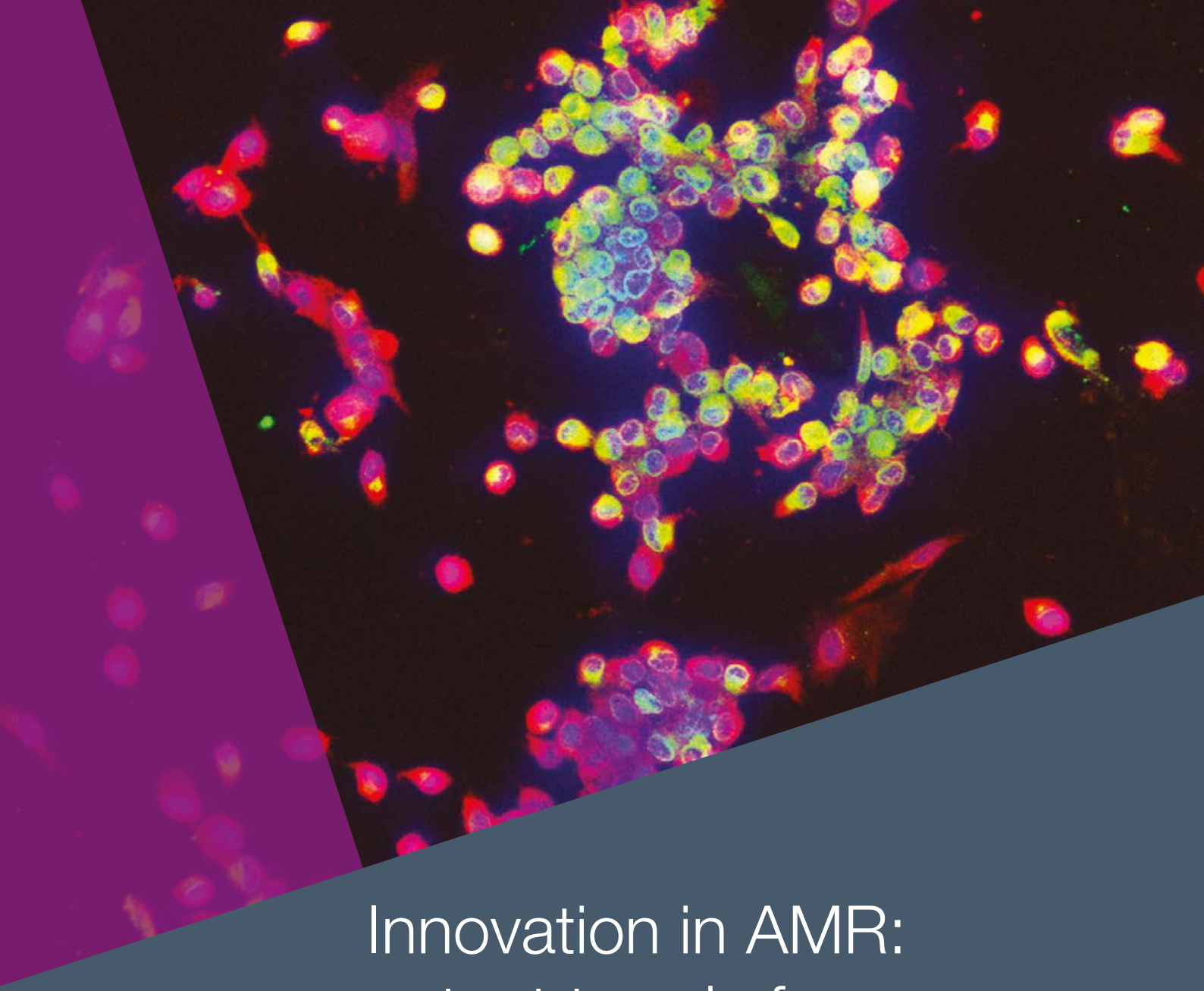


Innovation in AMR: patent trends for novel diagnostics

Challenge Prize Centre.

by nesta

LONGITUDE PRIZE

Marks&Clerk

Foreword

The Longitude Prize, a challenge with a prize fund of £10m, and an £8m pay-out to the winner, was launched in 2014 to encourage fresh thinking and innovation around antimicrobial resistance (AMR) – a key healthcare challenge of our time. While the development of novel antibiotics is essential in providing a last line of defence against rapidly evolving pathogens, reducing inappropriate prescription of existing antibiotics is also vital. This is where point-of-care (POC) diagnostic devices come into play. By giving clinicians better means of testing patients, POC devices facilitate better decision making – ensuring antibiotics are only prescribed when necessary and that the correct and most effective antibiotics are dispensed.

In recognition of the important role that POC devices will play in tackling AMR, the Longitude Prize was launched by the UK Prime Minister at the 40th G8 meeting, and has since been developed and run by Nesta, a global innovation foundation. The Longitude Prize is just one of many challenges being facilitated by Nesta and within the Challenge Prize Centre. The aim of the challenge prize methodology is to unlock innovation and develop solutions to some of the biggest challenges of the 21st century, from encouraging digital inclusion to building sustainable economies.

Methodology

Research for this report was undertaken by CPA Global, the world's leading Intellectual Property (IP) management and intellectual property technology company.

Phase I of the search comprised a patent key-word search of 3303 patent families which were screened manually with 738 patent families eventually shortlisted for relevance. These families were categorised based on a custom-built taxonomy covering assay technologies, device or apparatus technologies and pathogen types. These families were then subjected to a relevancy definition. This assessed point-of-care diagnostic methods or devices for World Health Organisation (WHO) listed antibiotic resistant bacteria and important infectious diseases.

In Phase II the analyst categorised all the 738 relevant families based on a custom-built taxonomy covering assay technologies, device or apparatus technologies, type of pathogens and advantages of the technologies.

Based on the database created in Phases I and II, Phase III involved the analysis and synthesising of patent information to gain intelligence in this technology area. The analysis addresses technology trends, major applicants and their profiles and important technologies appearing in patents.

A team from Marks & Clerk, comprising Paul Chapman, Rebecca Brooks and Laura Carney then carried out further analysis of the data. This analysis aimed to identify the key trends within the data, and is the basis of this report.

In US colleges and academic institutions, researchers are encouraged to file patents on newly created techniques and technologies. Success is often measured through high levels of technology transfer and patents and many of the most prestigious colleges are equipped with departments to support research groups to achieve this.

This culture has until late not been reflected widely in European universities, where a more traditional path of publication and obtaining grants remains the norm. This difference in culture could go someway to explaining the much larger numbers of patents filed by US academics in relation to their European counterparts.

Introduction

Paul Chapman
Partner, Marks & Clerk and member of Longitude Prize advisory panel.

Antimicrobial resistance (AMR) remains a foremost global health challenge. While there has been increased government financing to develop novel antibiotics against ever evolving pathogens, inappropriate prescribing in humans and the widespread use of antibiotics in livestock remain routine.

One of the keys to reducing unnecessary use of antibiotics in human health is to move from prescribing based on symptoms to an approach which relies on biological tests. Without practical, affordable point-of-care (POC) tests however, medics will continue to diagnose based on symptoms, and patients will continue to receive antibiotics unnecessarily. As things currently stand, common ailments such as sore throats are often treated with antibiotics — when in fact they are often symptoms of viral infections. Antibiotics have no positive impact on viral infections and can cause harm by increasing antibiotic resistance. By giving clinicians simple and rapid means of testing for bacterial infection, better POC diagnostics will help ensure that antibiotics are used only when appropriate and necessary.

On the research side there has been an increase in scientific and technical work to develop emerging technology and adapt existing technologies aimed at creating new tools to diagnose infectious disease. The majority of patent applications we see in this analysis are in the category of assay or test strip-based solutions – similar to diabetic blood tests and aim to confirm the presence of bacterial infections instantly. Alongside this are a number of other technologies seeing significant investment, including biosensors, which use living organisms to detect pathogens, hand-held and mobile devices, which facilitate more convenient testing and high throughput technologies, which harness increasingly sophisticated data analysis tools – all of which open up new fronts in the effort to contain AMR.

The European Patent Office's most recent annual report revealed that 'medtech' is now the most popular category for patent filing globally. There were 12,263 medtech patents filed in 2017, a 6.2% increase on the previous year. While not all of these patents will be focused on diagnostics or AMR, the trend towards increasing innovation in the development of diagnostic technology is to be welcomed.

Researchers are also taking advantage of increasingly sophisticated mobile technology. 66 patent families now relate to hand held or mobile devices and, indicative of growth in this area, 44% of these patents have been within the last five years.

We know technologies are being created which could lead to effective tests.

Last year the World Health Organisation (WHO) issued a list of 'priority pathogens' – 12 pathogens that pose the greatest risk to human health and some of which exhibit resistance to multiple antibiotics. While it is too soon after the WHO publication to see any resultant filing activity, the percentage of applications specifically mentioning the types of bacteria in the WHO list appears to have reduced dramatically in the last five years. However, despite this decline, the percentage of filings relating to the detection of bacteria has increased.

It is now three years since the publication of our first Longitude Prize Patent Report. As we reveal in this report, there have been increases in research and patent filings on diagnostic technologies. However, it remains to be seen if these technological advances translate into successful, accessible products.

Paul Chapman

Kevin Outterson
Professor of Law at Boston University School of Law. He is a member of the Longitude Prize Advisory Panel, the Executive Director of CARB-X, and Director of Social Innovation in Drug Resistance (SIDR) at Boston University.

The world desperately needs a life-saving diagnostic device that changes antibiotic clinical practice. The Longitude Prize has 75 registered teams that are competing to develop the most impactful point-of-care (POC) test, but we don't yet have a winner for the Prize.

Research funders continue to support innovation, including CARB-X, the public private partnership that I lead. We support early antibacterial research projects, providing millions of dollars to the best ideas out there. We hope that others fund and invest in high-potential POC products that will allow medical professionals to base prescribing decisions on the result of a biological test rather than on symptoms.

Additional financing to Longitude Prize teams and other test developers would help speed innovations highlighted in this report to market.

Of course, I hope that one of the CARB-X supported companies may eventually go on to win the Longitude Prize. However, I suspect that crossing the finish line on this challenge will require more than just outstanding scientific innovation.

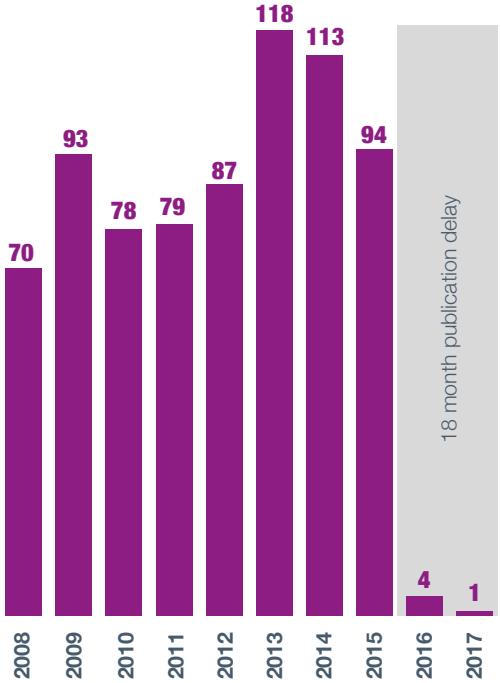
Part of the problem is the difficult bench science, but an even greater challenge may be how people and our health systems use diagnostic devices. Everyone says the world wants a rapid POC diagnostic for pathogen identification and antibiotic susceptibility, but companies don't see those desires translated into sales revenue. These devices won't magically appear without the structures that build, distribute, sell, use and regulate them.

The European Commission, the Wellcome Trust, and many researchers have joined together in a four-year project called VALUE-DX, part of the Innovative Medicines Initiative. This project is a good first step to assess the market potential and impact of POC tests. They aim to close the gap that prevents a great device from actually saving patients from drug-resistant bacterial infections.

Working together, all of the stakeholders in this area can change human behaviour through innovation in both bench science and the social sciences. Nothing less will yield success against drug-resistant bacterial infections.

Kevin Outterson

Filing figures 2008 – 2017



Overall filing trends

The last 10 years has seen a general increase in the number of patent filings relating to POC diagnostics aimed at pathogens and infectious diseases. Following an initial increase in filings between 2008-2009, the number of filings in this area stagnated in 2010-2011, a possible consequence of the 2008 financial crisis. Since then however numbers have recovered and reached their highest levels in 2013, when 118 filings were made.

Since 2013, the annual number of filings has been slowly declining, although we don't yet have a complete picture of filings in this area for 2016 and 2017 due to the 18-month delay in publication.

The US is currently the clear front runner for patent filings in the area of POC diagnostics for pathogens and infectious diseases. Over 60% of patent families (corresponding to 450 patent families) covering inventions in this area originated in the US, compared to 8% in the UK, the second largest source for developments in this field, followed by 6%, 4%, 3% and 2% in Europe, Japan, Korea and China, respectively. It is interesting to note that the filings in China appear relatively low compared to elsewhere, despite China being second overall in terms of all patent filings worldwide. This may point to Chinese companies being slow to pick up on this issue, but given China's huge population and associated healthcare burden, we expect to see China's patent filings in this area increase in coming years.

The majority of filings relating to POC diagnostics focus on the detection of bacterial and viral infections, there are however varying focuses in different geographies. In the US, filings relate to the detection of MRSA, Enterobacteriaceae (particularly *E. coli* and *Klebsiella*) and *Streptococcus pneumoniae*, in addition to the detection of viral infections such as seasonal influenza and Hepatitis B. The majority of these US patent families relate to cartridge- or cassette-based immunoassay systems, which allow for rapid testing of biological samples and the quick, sterile disposal of the cassette or cartridge. Filings in the UK do not generally focus on any one pathogen, but relate more generically to immunoassay (ELISA- and fluorescence-based) approaches, lateral flow devices, thermal cycling and isothermal amplification-based nucleic acid approaches, and fluorescence resonance energy transfer (FRET) techniques.

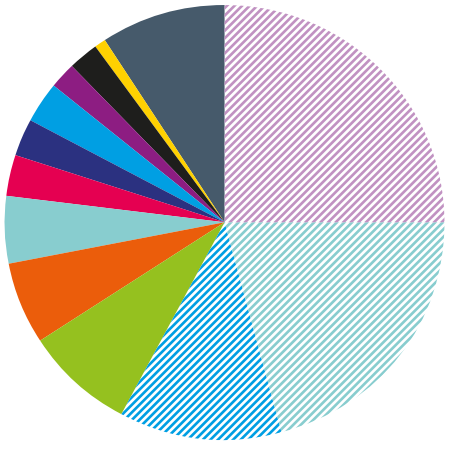
General trends in worldwide filings in this area over the last 10 years vary according to country. There was a general downward trend in filings in the UK, Korea, Japan and via the European Patent Convention, whereas there was a general upward trend in South Africa, China and Australia. In South Africa, 75% of patent families filed in the last 10 years having been filed between 2013 and 2017. South Africa as a country spends 9% of GDP on healthcare, higher than the average for other countries classed as 'middle income countries', reflecting the government's constitutional commitment to universal healthcare as a means of facilitating development. While South Africa's diagnostics industry remains nascent, the market has been growing steadily in recent years according to the South African Medical Technology Industry Association (SAMED), which is encouraging collaboration between overseas companies and small local players. Increasing levels of filing from South Africa could be a theme to watch in future reports therefore.

In the US, the number of patent families has been fairly consistent, with 46% of patent families filed in the US in the last 10 years having been filed between 2013 and 2017.

Filing figures by country 2008 – 2017

Source country	Number of patent families	% filed in last 5 years (2013–2017)	% Granted
United States	450	46	38
United Kingdom	58	40	31
EPC	42	36	43
Korea	27	37	70
PCT	23	48	26
Japan	21	33	76
China	15	60	73
Australia	13	62	38
Singapore	12	50	17
Germany	11	36	73
India	8	63	
South Africa	8	75	38
Finland	7		43
Taiwan	6	33	67
Denmark	5	20	60

Filing figures 2008 – 2017



Research into POC tests appears to be limited to a few countries – as indicated by the countries of first filing: 61% of all patent families (450 families) relating to POC solutions for identification of antibiotic resistance bacteria originate from US companies, universities or research institutes, for example. The second largest area for developments in this field is the UK, with 58 families originating from UK universities and industry.

A different picture emerges, however, when analysing the geographical distribution of total patent filings. On this account, while the US still leads with a total of 782 patent applications in the last nine years, we also see significant filings coming from, amongst others, Europe via the European Patent Convention (397 applications), Japan (199), Korea (86) and Germany (59). Among the BRIC countries (i.e. Brazil, Russia, India and China), most filings are taking place in China and India, with 244 and 105 applications, respectively.

POC patent filing: Who's leading the innovation?

Innovations in POC diagnostic tests for pathogens and infectious diseases are largely dominated by private companies and academic institutions. Almost two thirds of all applications originate from industry (60%), while approximately a third of all applications come from academic research institutes and universities (32%). The remaining eight per cent originate from individual inventors, hospitals and government agencies.

Many of the top players in this field are large US and European companies such as Abbott Laboratories, Philips and Siemens. Abbott Laboratories, a US company, is the most active player with 27 patent families broadly relating to cartridge- or cassette-based immunoassay POC devices for bacterial and viral detection. Most of these patent families (18) contain granted members. Abbott Laboratories has exhibited persistently high levels of activity in this field over the last nine years, with nine patent families in 2010, eight patent families in 2011 and five patent families in 2014. This is in contrast to Philips, the second most active player in this field over the last nine years with 13 patent families in total, who has not filed any applications in this area since 2009 and appears to be exiting the field.

Interestingly, in April 2017, Abbott Laboratories agreed to the acquisition of Alere, Inc., another persistently active, top 10 filer in this field. This acquisition will considerably bolster capabilities in POC diagnostics. However, increasing consolidation in the field could also prove detrimental to smaller players in the market and is a trend that will need to be watched closely. Alere, Inc. is already making an impact in the POC diagnostic test field and offers a number of rapid diagnostics for the detection of MRSA, RSV, pneumococcal pneumonia, *E. coli* and influenza, amongst others, with positive identification within five to 30 minutes. More recently, it received FDA clearance for a rapid molecular test for RSV and Group A Streptococcus, as well as WHO prequalification for a number of HIV and syphilis tests.

A number of academic institutions are also particularly active. With the exception of the University of Edinburgh (which has filed four patent applications), the top 10 universities for filing in this field are all US-based. The University of California, Harvard University and John Hopkins University have filed 12, 11 and six patent applications respectively since 2008, and show persistent high level activity over the last nine years.

A number of patent applications come from government departments and state-run research agencies such as the US Department of Health and the Government of Singapore via A*STAR, a research institute in Singapore. Singapore may represent a future innovator in this area being one of the top 10 filers. In addition, some patent families have also originated from Singaporean companies such as MP Biomedicals.

There are also a large number of applications coming from small-and-medium sized enterprises (SMEs). Aptateck Bio, an Israeli company, develops immuno-diagnostic assays based on lateral flow devices (WO13105090A1) with signal amplification for labelled antibodies and aptamers (US2015160207). The technology is directed towards bacteria such as Enterobacteriaceae, MRSA, campylobacter and TB, as well as Hepatitis B.

i-calQ, a US-based company, offers smartphone-based quantitative POC integrated diagnostics with a biosensor that can be used in combination with any smartphone camera and operating system (US8889424B, US9322767B and US2013273528A). The product is already available and may offer easy access and low-cost POC diagnostics.

Another US-based company, Church & Dwight, has also developed a number of diagnostic tests based on lateral flow technology, one of which is incorporated into a cassette type device and provides audio feedback (US2016027283A). Canadian company Fio Corp has two patent families in this field (US2014324373A and US2011165688A) for handheld POC diagnostics for detection of malaria and bacterial infections. This technology is used in combination with their key product, the Deki Reader, which is an *in vitro* diagnostic device for use with rapid tests.

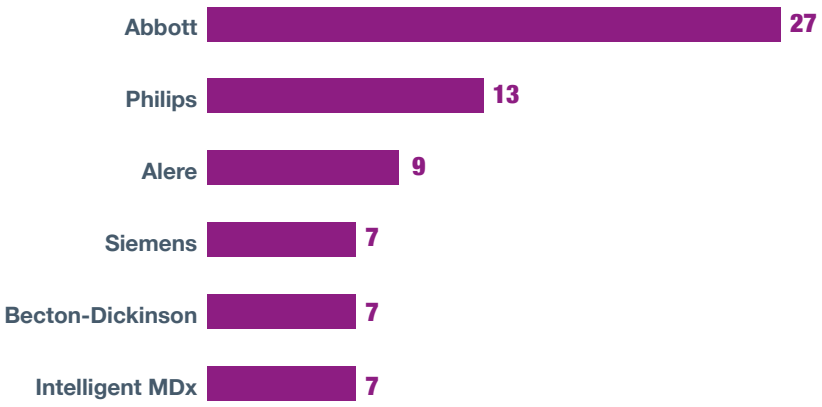
US-based Quest Diagnostics, Inc. has filed applications (US2015087545A and US2013022963A) relating to the detection of MRSA in biological samples and direct amplification and detection of pathogens including MRSA, *Pseudomonas aeruginosa* and seasonal influenza using real-time PCR. DST GmbH is a German company with patent families (US2015377874A, WO13026808A1, US2013022965A and US2012208205A) relating to POC assay technologies. Current products focus on handheld POC allergy diagnostics and ELISA kits for total IgE detection.

"Interestingly, in April 2017, Abbott Laboratories agreed to the acquisition of Alere, Inc., another persistently active, top 10 filer in this field. This acquisition will considerably bolster capabilities in POC diagnostics."

These are just a few examples of the variety of technologies being developed by SMEs. It is important to see development by SMEs as such companies are often seen as being able to bridge the gap between university/research institute development and commercialisation by large multinational companies.

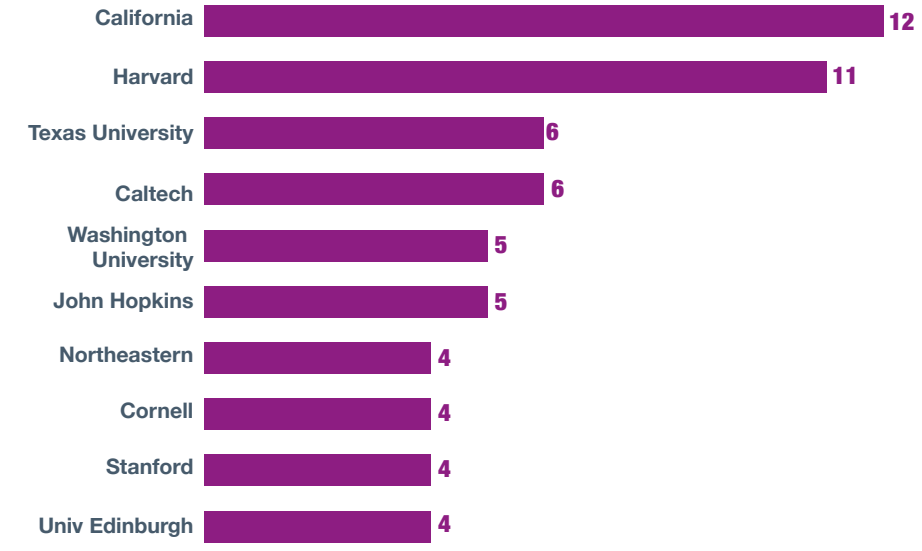
Patents filed

Top filing companies



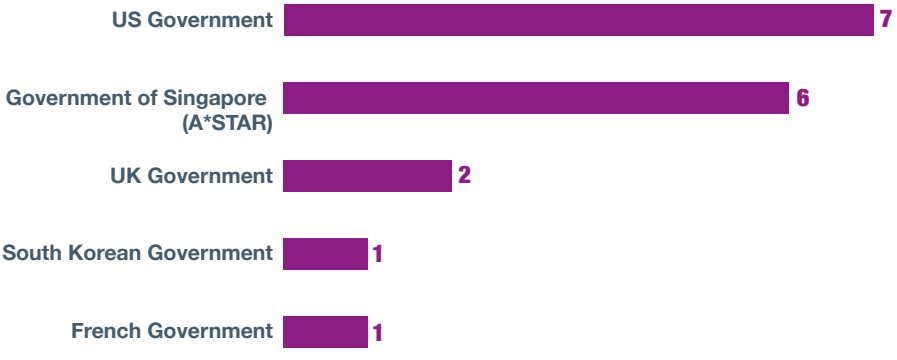
Patents filed

Top filing universities



Patents filed

Top filing government agencies



"It is important to see development by SMEs as such companies are often seen as being able to bridge the gap between university/ research institute development and commercialisation by large multinational companies."

Patents by pathogens

Analysis of recent patent filings reveals that, of the 374 patent applications indicating the pathogen type, the majority relate to detection of bacterial infection, with around a third relating to detection of viral infection, and a minority relating to fungal or parasitic infections.

Interestingly, although the relative numbers of patent filings have decreased in the last five years, the percentage relating to the detection of bacteria has increased since our previous report from 51% to 81%. This may point to increasing awareness of antibiotic resistance and misuse, and the importance of detecting bacteria correctly. Correctly detecting whether an infection is bacterial or viral in origin will undoubtedly reduce inappropriate use of antibiotics, and identifying a particular bacterial species and susceptibility of antibiotics will enable the correct narrow-spectrum antibiotic to be chosen.

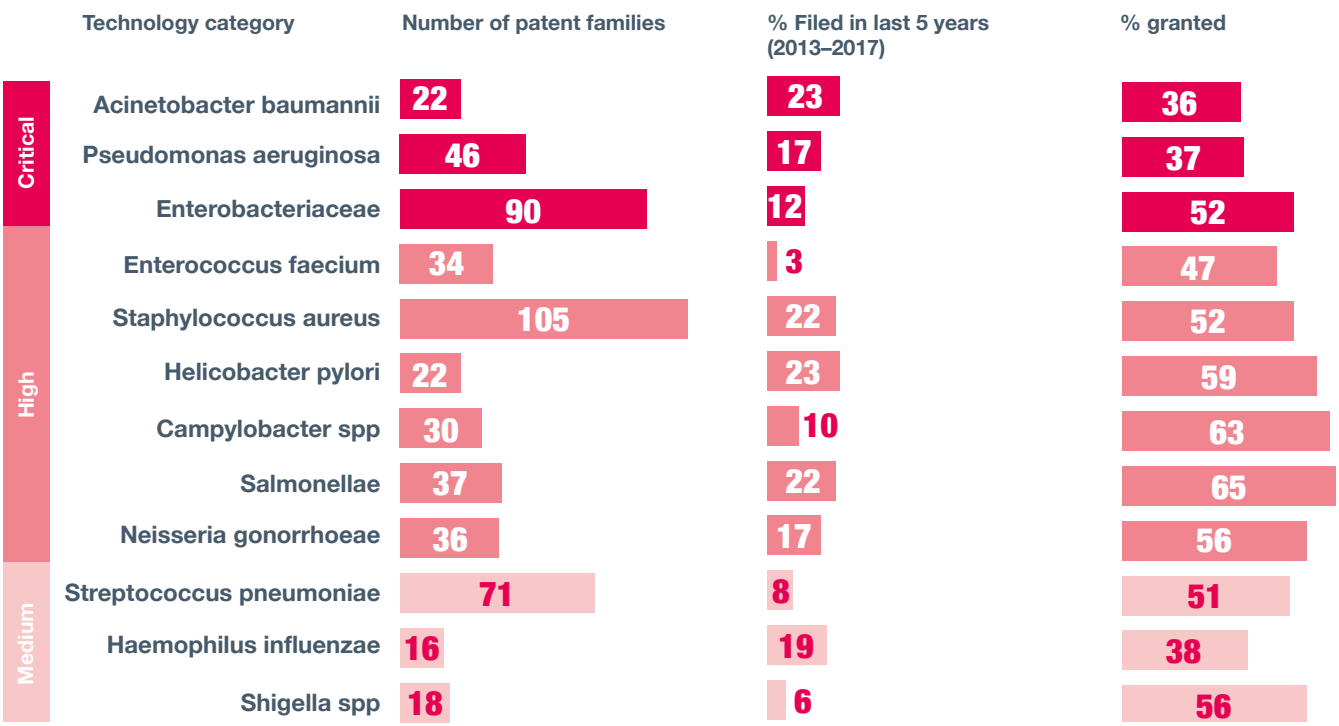
Antibiotics can be split generally into two separate camps: broad-spectrum antibiotics, which work on a wide range of bacteria, and narrow-spectrum antibiotics developed for a specific bacterial infection. Prescribing broad-spectrum antibiotics is linked to the increased development of AMR and increases personal risk through the destruction of the body's natural non-pathogenic bacteria. Thus, there is a significant role for narrow-spectrum, more specific antibiotics and diagnostic tests, which are able to specifically identify particular microorganisms.

A significant number of the pathogens identified in the WHO list are Gram-negative bacteria, such as *E. coli* and *Klebsiella*. These pathogens are often healthcare-associated and are linked to the development of serious bloodstream infections, of particular concern in hospitalised and elderly patients.

WHO pathogens versus patent filing since 2008

	Technology Category	2008	2009	2010	2011	2012	2013	2104	2015	2016	2017
Critical	Acinetobacter baumannii	3	3	5	5	1	1	3	1		
	Pseudomonas aeruginosa	5	11	6	9	7	3	5			
	Enterobacteriaceae	13	20	11	18	16	4	4	3		
High	Enterococcus faecium	2	8	15	6	2	1				
	Staphylococcus aureus	12	21	22	14	12	8	7	6	1	1
	Helicobacter pylori	3	4	3	1	5	1	2	2		
	Campylobacter spp	4	5	7	5	5	1		2		
	Salmonellae	5	4	7	5	8	4	2	2		
	Neisseria gonorrhoeae	5	7	8	5	5	2	2	2		
Medium	Streptococcus pneumoniae	9	16	18	13	8	1	3	2		
	Haemophilus influenzae	5	2	2	1	3		3			
	Shigella spp	5	2	4	2	4			1		
	Other	5	6	8	6	8	6	9	4		

WHO pathogens versus patent families and patents granted



Although publication of the WHO list is too recent to be able to have led to patent filings as yet, it is interesting to note that many microbial detection patent applications are nevertheless directed to the detection of bacteria on the WHO list.

As can be seen from the above table, all the bacterial species identified in the WHO list are mentioned in patent applications directed to bacterial detection (however, the data doesn't reveal whether the technologies disclosed in the identified patent applications are currently feasible and if there are any commercial product offerings).

Despite the WHO pathogens being mentioned in patent application, the relative percentage of applications specifically mentioning the types of bacteria appears to have reduced dramatically in the last five years. Also, perhaps worryingly, some of the most critical bacteria in the list, such as *Acinetobacter baumannii*, do not appear to be targeted significantly in terms of detection.

The table to the left shows a more detailed timeline of patent filings in which the patent specifications specifically mention detection of the bacteria identified in the WHO report. As shown, there appears to have been significant activity between 2009 -2012, but this looks to have tailed off more recently. Whilst it is difficult to be certain as to a reason for this, it may be that diagnostic device/assay developers have been focussing on more broadly applicable devices/assays, rather than looking to target specific bacteria. It will be interesting to see if the publication of the WHO report leads to a change in focus going forward.

Technology

Assay versus device

Diagnostic inventions can be grouped into those relating to a method or service (the “assay”) and those directed to a kit or device to be used in the field.

Analysis of POC diagnostic patent family filings since 2008 indicates that assay filings (49%) are more popular than device (33%) filings. While the reason for this difference is not entirely clear, it is possible that applicants may consider the protection of an assay, which can then be used with any device, to provide broader protection than for a device alone. Some applicants may also find it more cost-effective to focus on the development of an assay, particularly when the assay can be used with existing platforms. For some applicants, however, a filing directed to a device can be particularly useful in protecting a platform technology which may then be used with any number of methods.

The remaining 18% of filings are directed to technology for both an assay and a device. With advantages to gaining protection for assays and devices, it is worthwhile trying to obtain protection for an assay and a device in a patent filing, if possible.

In the device category, the most common type of filing relates to lateral flow assays or test strips (185 families), closely followed by cartridge- or cassette-based devices (133 families). However, many of these applications were filed prior to 2013. While fewer applications have been filed which relate to high throughput technology or mobile/handheld devices, a greater proportion of these (43% and 44%, respectively), were filed within the last five years.

Emerging methodology over the last five years includes enzymatic assays and general biomarker assays, where assay details are unspecific in a patent application, but don’t readily fit into an existing assay category. Nucleic acid assays and immunoassays also remain popular. Breaking down the filings by technology for each pathogen, we find that the most popular assay for the detection of bacteria is the nucleic acid assay, followed by the immunoassay. Similar patterns emerge for the detection of parasites and fungi, while the most popular assay for the detection of viral pathogens is the immunoassay.

Lateral flow and cartridge-based devices prove popular for the detection of viruses and bacteria. The majority of devices for parasite or fungi detection are microarrays or other miscellaneous devices.

Focus on mobile technology

There has been a recent increase in mobile technology and hand-held devices, with 44% of all filings in this area filed within five years. This is not unexpected. Given the portability and prevalence of mobile phones, mobile technology promises diagnostics that reach even the most remote areas, without the need for laboratory testing or complex and potentially expensive equipment.

Recent developments include a microchip adapted to perform an enzyme-linked immunosorbent assay (ELISA) by Brigham and Women’s Hospital (US 2014/0242612). A mobile device is then used to image and analyse a colorimetric result from the microchip ELISA to determine biomarker concentration.

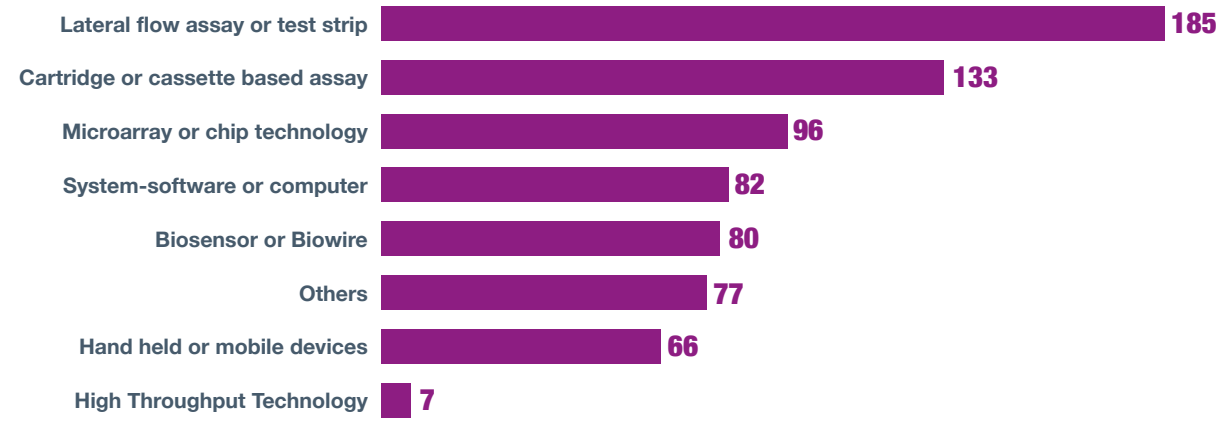
Another recent mobile device application is WO2016064917 from Princeton University. This filing is directed to a signal enhancing detector, for example a microfluidic device, which is configured to give an output reading, together with a device configured to receive this reading, for example, a smartphone.

Developments in the hand-held device area include, for example, a thermal cycling amplification-based POC diagnostic device by Click Diagnostics (US9623415). The device can be battery-powered to enable detection and diagnosis at any site, while detection can occur by a colorimetric or luminescent reaction.

Technology heat map

		Assay										Device						
		Nucleic acid assays	Protein assays	Enzymatic assays	Biomarker assays	Fluorescent immunoassay	ELISA immunoassay	Immunoassay	Volatile gas	Mass spectrometry	CRISPR	Biosensor or biowire	High Throughput	Microarray or chip	Cartridge of cassette	Lateral flow	Hand-held or mobile	System
Pathogen	Virus	52	1	3	6	35	24	66	3	3	1	10	1	22	32	45	19	27
	Bacteria	133	3	4	16	54	39	81	4	9	6	20	2	36	42	51	17	35
	Fungus	17		1	2	13	3	11		1	1	1		7	2	4	4	7
	Parasite	10		1		9	4	7			1	2		9	2	3	3	6
Antibiotic resistant bacteria																		
Critical	Acinetobacter baumannii	10		1	1	4	3	7		1	1			1	1	2	1	5
	Pseudomonas aeruginosa	28		3	1	16	5	12	1	2	1	3	1	4	5	4	2	9
	Enterobacteriaceae	51	1	2	5	23	16	35	1	4	3	7	1	11	17	15	5	15
High	Enterococcus faecium	25			1	11	2	14		1	1	1		9	5	4	2	14
	Staphylococcus aureus	65	2	5	2	31	13	36	2	4	3	8	1	18	19	16	11	19
	Helicobacter pylori	9	1			3	4	8	1					4	2	8	2	3
	Campylobacter spp	16	1	1		7	7	13		1		1		2	8	6	2	5
	Salmonellae	21		1	1	8	5	13	1	2		3		3	5	12	4	4
	Neisseria gonorrhoeae	21		1	2	6	8	14			1	1		5	6	9	4	4
Medium	Streptococcus pneumoniae	36	1	2	4	21	11	32	2	3	1	4	1	15	13	16	10	19
	Haemophilius influenzae	9		1		8	4	4		2				2	1	1		3
	Shigella spp	12			1	4	3	6		1				3	2	4	3	4
Disease	Hepatitus B	22			3	22	17	36			1	3	1	15	14	20	9	17
	Meningococcal disease	1				1	2	2										1
	Pertussis (whooping cough)	8				8	2	5		1		1		7	1	3	2	7
	Rotavirus gastroenteritis	5		2		5	3	5				1		1	3	3	1	
	Seasonal influenza (flu)	33	1	2	4	22	11	36			1	6		13	14	17	13	14
	Tuberculosis (TB)	62	3	1	11	27	21	29	5	5	2	7	2	19	12	17	8	16

Number of patent families



Regulation of mobile technology

Although the use of smartphones represents an exciting development in the field, a diagnostic app could be classified as a medical device. Any diagnostic apps developed will need to comply with the relevant national regulations to ensure that the app is suitably safe and reliable. Guidance as to whether an app is considered to be a medical device in the UK is available from the MHRA www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety.

Once a medical device has been placed on the market, the manufacturer is responsible for monitoring the product and reporting serious adverse incidents to the competent authority. Given that apps often require regular updates, applicants and manufacturers should therefore be careful to ensure that any updates to the app do not affect its safety and reliability. As mobile devices become more common in the field, we expect that regulators may look to include more regulation regarding the impact of any updates on the safety and reliability of the device.

Conclusions and implications on AMR

This report demonstrates that there is significant innovation in the diagnostic space that could potentially lead to tests coming to market that would avoid the unnecessary use of antibiotics and better target antibiotic therapy. However, the Longitude Prize, that currently has 75 teams competing from 14 countries, has received feedback from test developers that creates concern. Longitude Prize teams are struggling to attract adequate funding and investment to ready their tests for market and gather adequate data to validate tests and reach regulatory standards.

"This report demonstrates that there is significant innovation in the diagnostic space that could potentially lead to tests coming to market that would avoid the unnecessary use of antibiotics and better target antibiotic therapy."

The reasons for this are two-fold. Investors are concerned that price expectations are too low to assure return on investment and are not convinced that financing will be available either from health systems or funders to help create this new market. This is a warning to policy makers that initially there will likely be a need to ring-fence funds to assure that products are purchased and new norms are created whereby biological testing before antibiotic prescribing becomes the norm. For low and middle-income countries (LMICs), there will likely be a need to prime the market in the same way that has been done with diagnostics for AIDS, tuberculosis and malaria. Unfortunately, to date there have been no commitments to guarantee initial purchases for high-income or LMIC markets.

If commitments can be made to purchase products that meet minimum specifications in developed countries and LMICs, this would likely have a dramatic impact on this market, increasing the chances of reaching global goals to reduce unnecessary use of antibiotics and to better target their use.

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The Longitude Prize

The Longitude Prize is managed by Nesta's Global Health Team at the Challenge Prize Centre (CPC). The CPC was established to increase practical evidence and understanding about challenge prizes so they can be used effectively by governments, charities and businesses to have a tangible positive impact on society. The CPC designs and manages prizes on behalf of clients.
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