Microbial infection: Point-of-care diagnostics
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Foreword

Nearly 90 years have passed since Alexander Fleming discovered the first antibiotic - penicillin. Since then, antibiotics and other antimicrobial drugs have revolutionised every aspect of modern medicine. Without antimicrobials, current routine surgery and common infections could be fatal.

As the use of antimicrobials has increased, so too has microbial resistance to these drugs. Fleming, himself, predicted the rise of resistance in his 1945 Nobel lecture and, today, politicians to researchers warn that we are rapidly approaching a “post-antibiotic era” – an era in which a common infection can once again kill. This is an urgent global issue.

Blame for the development of antimicrobial resistance can be pointed at the overuse of and overreliance on broad spectrum antimicrobials. In a sense, antimicrobials are a victim of their own success; they are so effective that clinicians and patients alike have become too dependent on their function. With limited development of new antimicrobials, as was recently discussed in the UK Government’s report, Securing new drugs for future generations: the antibiotics pipeline, and the constant ability of microbes to evolve, we need a new solution. This requires intelligent use of current antimicrobials and more effective prevention to stop antimicrobial resistance from developing further.

It is now a year since the British public voted to make antibiotic resistance the subject of the Longitude Prize. Since then, the issue of antibiotic resistance has moved closer to the top of the global health agenda, and a coalition is taking shape to galvanise action. Pharmaceutical companies are beginning to pledge money towards new antibiotic R&D; many groups are working to study resistance; big livestock producers are phasing out wide antibiotic use in farming; and a lot more money is being pumped into research. A useful input is the series of reports published by the UK Government's AMR Review, headed by Jim O’Neill, which have shown the potential cost of antibiotic resistance could be as high as 300 million deaths and $100 trillion by 2050.

The Longitude Prize is just one part of this picture – but a crucial one. We have focused the prize on point-of-care (POC) diagnostics to reduce dependence on antibiotics as a means of tackling infections. At the moment, it is difficult for doctors to identify quickly which antibiotics are needed to treat an infection. If anyone can develop an easy and quick way to tell what infection a patient has and whether antibiotics are even needed (infections caused by a virus will not be affected by antibiotics, which will kill only bacteria), this would lead to much more targeted use of antibiotics and a much reduced threat from resistant strains.

We are grateful to CPA Global, Landon IP and Marks & Clerk for their support of the Longitude Prize. The patent landscape study presented in this report will be a very valuable tool for the judging panel when considering submissions.

Geoff Mulgan
Chief Executive of Nesta
Longitude Prize committee member
Marks & Clerk, CPA Global and Landon IP are proud to support the Longitude Prize and the important quest to find a solution for one of the greatest modern-day risks affecting people across the world: the rise of antimicrobial resistance.

Although this issue has been attracting headlines for some years now, we still face a serious threat from microbial resistance to drugs, compounded by misprescription of antimicrobials.

Our research into patent filings in the area of POC diagnostic tests gives an indication not only of the levels of research into such tests and the types of organisations applying for patents in this area, but also the focus of recent research. We analysed worldwide patent filings since 2009 in order to draw out key trends.

This is a critical time for investment into and the development and patenting of new POC technologies. Although our research revealed an overall decrease in annual numbers of patent filings for POC diagnostic tests in recent years, we hope that media and public awareness of the importance of POC diagnostics in the fight against antimicrobial resistance, a stronger focus and increased research investment by governments (especially in the UK and USA), together with initiatives like the Longitude Prize, will see an acceleration in patent filings in this area.

The picture emerging from our study shows the USA to be the clear leader in research into POC diagnostic tests, followed by the UK. Over half of all patent filings relating to POC diagnostics around the world were by private companies. While Abbott, the global healthcare company, is the leading individual filer of patent applications in this area, small to mid-sized entities (SMEs) represent 70 per cent of patent filings by private companies.

Over the past few months, the Nesta Longitude team has been encouraging submissions from around the world. Events across the USA, China, India, Europe and South America have attracted registrations from many different types of organisations worldwide. With innovators now able to submit their ideas to the Longitude Prize judging panel, we are excited at the prospect of finding an accurate, rapid, affordable, easy-to-use POC test that will be available to anyone, anywhere in the world.
Overall filing trends (five years from 2009)

The past five years have seen upwards and downwards movement in the number of patent filings for POC diagnostic tests in the field of antimicrobial-resistant organisms. While the number of patent families initially increased from 90 in 2009 to 100 in 2010, subsequent years have seen a reduction in filings (Fig. 1). It is likely that the global financial crisis was at least partly accountable for the dip, having led to a reduction in research and development budgets and funding available for private and public sector research.

However, the trend of decreased patent filings is expected to reverse over the next few years. The media and general public have become increasingly aware of antimicrobial resistance, to the extent that it was ranked in a public vote as one of the greatest modern-day risks, leading to the search for a POC diagnostic solution becoming the focus for the Longitude Prize. This will likely act as a stimulus for research, innovation and, consequently, patent filings in the area. The relatively limited number of recent POC diagnostic test patent filings, together with initiatives like the Longitude Prize, may lead innovators to the view that now is an opportune time for investment into, and the development and patenting of new POC technologies.

A more noticeable decrease in filings has been observed for individual applications (Fig. 1a). This suggests that applicants are adopting a more restricted filing strategy, with more recent applications limited to a smaller number of countries compared to previous years.

At present, the USA leads the way as the jurisdiction in which applicants file the first patent application in any given POC patent family, with 78 percent of all first patents filed there (Fig. 2). It is no surprise that the USA, home to the world’s largest economy, is the destination of choice for first filing, both for US entities and many foreign entities. This is the case not only in POC diagnostics, but also in the wider biotechnology field and, in fact, across most technologies.

Second only to the USA, the UK has been the destination for a significant number of first filings (26). Other developed countries show lower levels of activity, with Singapore, Germany, Australia, and South Korea following behind the UK and the USA as destinations for first filing.

A review of the POC test patent applications first filed in the UK highlighted a number of trends. Unlike some US applications, patent applications first filed in the UK appear to be primarily directed towards devices or a method in combination with a device. In particular, a number of UK first-filed applications are related to disposable assay cartridges, where a biological sample can be placed directly into the cartridge for subsequent assessment before disposal. This disposable feature is important for clinicians when requiring a quick and sterile change-over of equipment at the point of care between patient samples. Many of the UK patent applications do not relate to a particular pathogen, but are, instead, purposefully broad in order to cover a device that could diagnose any number of infections. The UK patent applications that are more specific are directed towards the diagnosis of bacterial rather than viral infection.
While research into POC tests appears to be mostly limited to a few countries – as indicated by the countries of first filing – a different picture emerges when analysing the geographical distribution of total patent filings. Although the USA again leads with a total of 330 patent applications since 2009, Europe also features strongly, with 139 patent applications in the same period. A significant number of patent applications have also been filed in China (89) and India (29) (Fig. 3).

**Fig. 3**
Total patent applications for point-of-care diagnostic inventions by geography

The USA and Europe are the two most significant markets where entities are seeking protection. Among the BRIC countries, most filings are taking place in China and India.
Like in many other biotechnology sub-fields, private companies and academia are driving the innovation of POC diagnostic tests (Fig. 4). Of the applications from private companies in this field, over 70 percent of patent filings (121 patent families out of 170 from private companies) are from small to mid-size entities (SMEs – Fig. 3). However, universities follow closely behind with 118 families.

To take a few examples, the University of California has filed eight patent applications since 2009 (Table 2). In the same period, Harvard University filed four patent applications. Brigham and Women’s Hospital and Massachusetts General Hospital, both affiliates of Harvard Medical School, have filed four and three applications, respectively (Table 3). Combined with the four applications in Harvard University’s own name, this makes the Massachusetts-based university a key player in the field.

No one SME dominates the field, with individual SMEs filing three patent applications, at most, since 2009. Most SMEs filed one patent application each in the same period. Of the 14 SMEs that have applied for two or three patent applications, two specialise in technology transfer. Another five are owned or controlled by larger entities.

In addition, government agencies from the USA, Singapore, and the UK have carried out research in this area, leading to a number of patent filings (Table 4), indicating that antimicrobial resistance is a key area of concern at government level. The most prominent player by far across the whole field is Abbott, which has filed 26 patent applications in the area of POC diagnostics since 2009, more than three times the amount of any other applicant. The majority of Abbott’s recent filings have focused on immunosassays and viral detection.

One example of an entity already making an impact in the POC diagnostic test field is Alere. Alere recently announced that it has won FDA approval for its iStrep A test, the first molecular test to detect Group A Streptococcus bacteria in throat swab specimens in around eight minutes. This technology is already in use in its corresponding influenza A and B test. Current pending applications by Alere focus upon the improvement of test devices generally (application WO2014/13996, for example) rather than a particular test or device.

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Innovation coming from SMEs

Nexus DX Inc, a company specialising in POC diagnostics, has filed two patent applications since 2009. One of these, application US2010/0323343, relates to methods and devices for the detection of analytes, such as influenza virus. The method in this application is described as utilising a sample collection device and a test strip, where readable lines will form if the patient is infected.

Similarly, Cellestis Ltd. (a top SME filer acquired by Qiagen N.V. in 2011) has filed a number of applications describing methods for measuring cell-mediated immune responsiveness in blood, which can be used to indicate if an individual is infected by a particular pathogen. These applications appear to be directed towards the further development of their QuantiFERON® technology, currently available as diagnostic tests for TB or CMV infection.

Fio Corp, an independent SME, has filed two patent applications since 2009. Application WO2010/099607 is directed towards a diagnostic test for the detection of malaria and severe bacterial infections. In particular, this test can distinguish between different strains of malaria and so is able to diagnose the resulting severity of the disease. Fio Corp’s key product is the Deki Reader, an in vitro diagnostic device for use with rapid diagnostic tests in order to deliver quality control and an objective analysis of results. This can be combined with Fionet mobile phone software to facilitate remote oversight.

Many entities are seeking to develop smartphone-like diagnostic devices. One SME, QuantuMDx, has developed a handheld DNA analyser (Q-POC™), which uses disease-specific cartridges to provide a molecular diagnostic result in 10–15 minutes. Tests are currently being developed for malaria, multi-drug-resistant tuberculosis and sexually transmitted infections.

Not surprisingly, two of the largest antibiotic manufacturers, AstraZeneca and GlaxoSmithKline, are looking to enter the POC test area. However, at present, this is not reflected in our data set. In 2012, these two companies launched an alliance geared towards pioneering a new approach to antibiotic research in Europe. Since then, the alliance has expanded to include the molecular diagnostic companies Cepheid and Cubist Pharmaceutical. Incorporating smaller companies into such alliances suggests the need for small and large entities to cooperate in the area; while the majority of filings originate from SMEs, an alliance with a larger company provides the resources to help facilitate product development. This alliance approach is expected to continue and expand over the next five years.

Fig. 5

Patent applications for point-of-care diagnostic inventions by private companies

Most filings in the private sector are by mid-size or small companies.
While certain entities in the POC test area are looking to develop a methodology and/or service – “the assay” – others focus more on the development of a platform technology in the form of a device or kit to be used in the field. However, there are a significant number of applications incorporating both an assay and a device.

Analysis of the technology in patent family filings since 2009 indicates that assays are the primary focus of many researchers, with 51 percent of patent families (170 in total) filed relating exclusively to assays (Fig. 6). Of patent families filed, 32 percent (107 in total) were directed to technology for an assay and a device, with the remaining 17 percent of patent families (55 in total) relating to apparatus device technology only. Within assay filings, 93 were nucleic acid-based and 82 were immunoassay-based (Fig. 7). The most popular device and apparatus filings were directed to microarrays (52), with 28 patent families related to biosensors or biowires (Fig. 8).

With devices and assays often going hand in hand, collaborations between assay and device developers can be beneficial to both parties and may increase in the future.
Type of pathogen

To date, the majority of applications in the POC test area have focused on bacterial or viral infection, with only 3 percent of applications directed towards the diagnosis of parasitic infections, and even fewer (2 percent) directed towards fungal infection (Fig. 15). Given that parasitic infections are of most concern in the developing world, it is perhaps unsurprising, although unfortunate that more is not being done in this area of detection. Within bacterial infections, antibiotic-resistant tuberculosis (TB) has been a major target, with 28 filings in the past five years (Fig. 16). A number of other applications were directed towards MRSA (8) or C. difficile (6). Reflecting the large variety of antibiotic-resistant bacteria, other applications have also been directed to Salmonella (3), Enterococcus (3), Borrelia (2), Shigella (1), Klebsiella (1), Pseudomonas (1), and Treponema (1).

In its report, Antimicrobial resistance: global report on surveillance 2014, the World Health Organization (WHO) identified three bacteria with very high rates of resistance in all WHO regions: Escherichia coli, Klebsiella pneumoniae, and Staphylococcus aureus. However, relatively few of the current POC diagnostic patent applications are directed towards E. coli or K. pneumoniae. These may well become a target for research into diagnostic tests over the next five years. Given the media attention surrounding MRSA, it is unsurprising that the second-highest number of patent applications for bacterial POC diagnostic tests is directed towards this infection. Mostly a hospital-acquired infection, MRSA can be life-threatening if the bacteria gets into the body. Notoriously difficult to eradicate, MRSA has subsequently become a major concern for patients following surgery or the insertion of an intravenous drip.

### Tuberculosis – still a killer

The position of TB at the top of bacterial POC diagnostic applications is due to the global TB epidemic in low- and middle-income countries, combined with a steady increase in antibiotic-resistant TB over the past 12 years. TB is the second leading cause of death from a single infectious agent, and nine million people worldwide fall ill from TB in 2013. Although access to TB care has improved dramatically since 2000, this has unfortunately coincided with a rise in antibiotic-resistant TB, with an estimated 450,000 people worldwide developing multidrug-resistant TB (MDR-TB) in 2013. Of those, nearly half died of MDR-TB. With the WHO aiming to expand rapid testing and detection of drug-resistant TB cases, there has been a clear push by the authorities to develop such diagnostic technology, which is reflected in patent filings. TB is a complex disease with a number of different stages. Some patients progress through each stage quickly. Other patients possess a latent and asymptomatic form of the disease, where bacilli remain in a cavity without spreading for a number of years.

In treating TB, it is particularly important to be able to distinguish between MDR-TB and non-MDR-TB. Such a diagnostic test would provide a real benefit to patients, enabling clinicians to quickly and effectively administer appropriate treatment to the individual, which could potentially prevent the progression of disease in MDR-TB patients.

**How TB infects a patient**

Diagram created with reference to: [www.tbonline.info/](http://www.tbonline.info/)

Inhalation of TB bacilli

*Fig. 9*

Patent applications (families) for point-of-care diagnostic inventions by pathogen type

<table>
<thead>
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<th>Pathogen</th>
<th>Number</th>
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<td>Bacteria</td>
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<tr>
<td>Virus</td>
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<td>Parasite</td>
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</tr>
<tr>
<td>Fungus</td>
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</table>

Numbers indicate numbers of patent families applied for between 2009 and 2013

Data incomplete for 2013 due to 18-month publication lag

Only patents specifying pathogens are counted

**Fig. 10**

Patent applications (families) for bacteria-related point-of-care diagnostic inventions by bacteria

- Mycobacterium Tuberculosis
- MRSA
- C. Difficile
- Other

<table>
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<tr>
<th>Pathogen</th>
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</tr>
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<tbody>
<tr>
<td>Mycobacterium Tuberculosis</td>
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<tr>
<td>MRSA</td>
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</tr>
<tr>
<td>C. Difficile</td>
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<tr>
<td>Other</td>
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</table>

Numbers indicate numbers of patent families applied for between 2009 and 2013

Data incomplete for 2013 due to 18-month publication lag

Only patents specifying bacteria are counted

**Fig. 11**

Patent applications (families) for virus-related point-of-care diagnostic inventions by virus type

- HIV
- Herpes
- HPV
- Dengue Fever
- Hepatitis

<table>
<thead>
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<th>Pathogen</th>
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<tbody>
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<tr>
<td>Herpes</td>
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<td>HPV</td>
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<tr>
<td>Dengue Fever</td>
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<tr>
<td>Hepatitis</td>
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</tr>
</tbody>
</table>

Numbers indicate numbers of patent families applied for between 2009 and 2013

Data incomplete for 2013 due to 18-month publication lag

Only patents specifying viruses are counted

**Fig. 12**
To reduce the chance of developing infection, many National Health Service (NHS) hospitals in the UK now screen patients for MRSA prior to a planned procedure. However, this is time and labour-intensive. It generally involves obtaining a sample from the patient, then growing the sample for a period of time to assess bacterial growth. Results typically take three to five days. A number of patent filings have consequently focused on the development of faster POC diagnostics for MRSA, thus reducing time and cost for the healthcare provider.

Within applications focused on the diagnosis of viral infections, POC tests directed to drug-resistant HIV are the most numerous, with nine applications filed in the past five years (Fig. 11). According to the WHO, by the end of 2013 an estimated 35 million people were living with HIV worldwide. The world’s leading infectious killer, HIV can be prevented from multiplying if patients take combination antiretroviral therapy (ART). Importantly, if a patient is on ART, their chance of transmitting HIV to a partner or their child dramatically decreases. However, the WHO estimates that around 10 percent of patients are ART-resistant, a percentage that is increasing over time.

The majority of current patent filings have focused on the detection of one single microbe. Whilst it is important to detect specific infections, there is a desire for a POC diagnostic test that can detect multiple infectious agents, or more broadly, diagnose whether an infection is viral or bacterial. A product that can establish whether an infection is bacterial or viral would be of great benefit in preventing the misuse of antibiotics for viral infections.

It is clear that the emergence of antimicrobial-resistant microorganisms is of increasing concern to authorities across the world. One example being closely monitored is carbapenem-resistance. Considered a last resort of treatment, carbapenem is a powerful antibiotic prescribed to treat Enterobacteriaceae infections, which cause bladder, lung, and blood infections. Left untreated, these infections can progress into life-threatening septic shock. Once a patient has a carbapenem-resistant infection, few antimicrobial treatments remain.

**Looking ahead**

We envisage that the next few years will see a reemergence of antimicrobial research in combination with the development of POC diagnostic tests. Together, the discovery of new antibiotics with the development of POC diagnostic tests will be fundamental for the safeguarding of the effective treatment of common infections for years to come.
Methodology

The patent filing data analysed in this report was provided by Landon IP, the specialist patent analytics and consulting arm of CPA Global.

Patent landscaping was carried out for patent applications filed around the world from the earliest priority date after 1 January 2009. During the search, USPTO, International Patent Classification (IPC), and Cooperative Patent Classification (CPC) codes with direct relevance to point-of-care (POC) diagnostics were combined with keywords related to infectious diseases. The keywords covered the most significant human pathogens identified by the US National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC) as having potential for developing resistance. Companies with known history of developing POC diagnostic tests were also searched. The landscape search was conducted in late October 2014 using PatBase.

The results from the search queries were analysed by a Landon IP technical expert with an advanced degree in biotechnology, who manually screened the patent applications for relevancy. Patents deemed not relevant were removed from the final result set. The technical expert further categorised all the relevant patent families based on a custom-built taxonomy covering assays, devices, types of pathogens and advantages.
The contributors are grateful to Laura Carney of Marks & Clerk for her assistance in drafting written analysis of the data. Potential Longitude Prize competitors should review Nesta’s FAQs for queries about their own intellectual property and responsibility to consider patentability and freedom-to-operate issues before entering the Prize. Professional advice should also be sought, where appropriate.
About the Longitude Prize
The Longitude Prize is a challenge with a £10 million prize fund to help solve the problem of global antibiotic resistance. It is developed and run by Nesta, the innovation charity. The Prize was announced by British Prime Minister David Cameron at G8 2013 and is being supported by Innovate UK (formerly the Technology Strategy Board) as funding partner. The Prize commemorates the 300th anniversary of the Longitude Act (1714) when the British government threw down the gauntlet to solve one of the great scientific challenges of that century: how to pinpoint a ship’s location at sea by knowing its longitude. The British public voted for antibiotic resistance to be the focus of the Longitude Prize. For further information, please visit: www.longitudeprize.org.

About Marks & Clerk
Marks & Clerk is recognised as a world leader in intellectual property and is proud to be a supporter of the Longitude Prize. Our patent attorneys, trade mark attorneys, solicitors and consultants offer a comprehensive range of services – covering patents, trademarks, designs, domain names and copyright. This includes protection worldwide, portfolio management, IP strategy, commercialisation, licensing, enforcement, due diligence, litigation and valuation. The extent of our resources means we are able to offer expertise covering an exceptionally diverse range of technologies and commercial sectors. Healthcare inventions are one of our key specialisms. Our international network of 17 offices – in the UK, France, Luxembourg, Canada, China, Hong Kong, Malaysia, Singapore and Australia – and unrivalled IP connections around the world, enable us to provide single point access to a consistently high-quality and cost-effective service both locally and globally.

For further information, please visit: www.marks-clerk.com.

About CPA Global
CPA Global is the world’s leading provider of intellectual property (IP) management services and software. With offices across Europe, the United States and Asia Pacific, CPA Global supports many of the world’s best known corporations and law firms with a range of IP and broader legal services, helping them manage risk, cost and capacity. CPA Global assists corporates and law firms in managing valuable IP rights, such as patents and trademarks, ensuring that IP portfolios are protected, maintained and regularly reviewed to optimise value. Working closely with its clients, CPA Global ensures they have the best information on which to base IP decisions, and the best support in terms of helping implement those decisions. Founded in Jersey, Channel Islands in 1969, CPA Global today employs some 2,000 people, serving clients’ needs in 200 jurisdictions through its own offices and an extensive agent network.

For further information, please visit: www.cpaglobal.com.

About Landon IP
As the specialist patent analytics and consulting arm of CPA Global, Landon IP is a leading global provider of professional business support services throughout the intellectual property lifecycle and across all technologies. Landon IP’s primary services include patent searching, technical literature searching, analytics and technology consulting, global IP information research and retrieval, and patent, legal, and technical translations. The company’s activities cover every possible type of search, including: patentability, innovation screening or accelerated examination; freedom-to-operate, product clearance or infringement detection; invalidity, opposition, post-grant proceedings or strength testing; and state of the art or collection. The company also provides advanced training in patent searching worldwide through Patent Resources Group (PRG), a wholly-owned subsidiary. The patent landscape study for the Longitude Prize that forms the basis of the Microbial infection: Point-of-care diagnostics report was undertaken by Landon IP’s Analytics and Technology Consulting Group.

For further information, please visit: www.landon-ip.com.