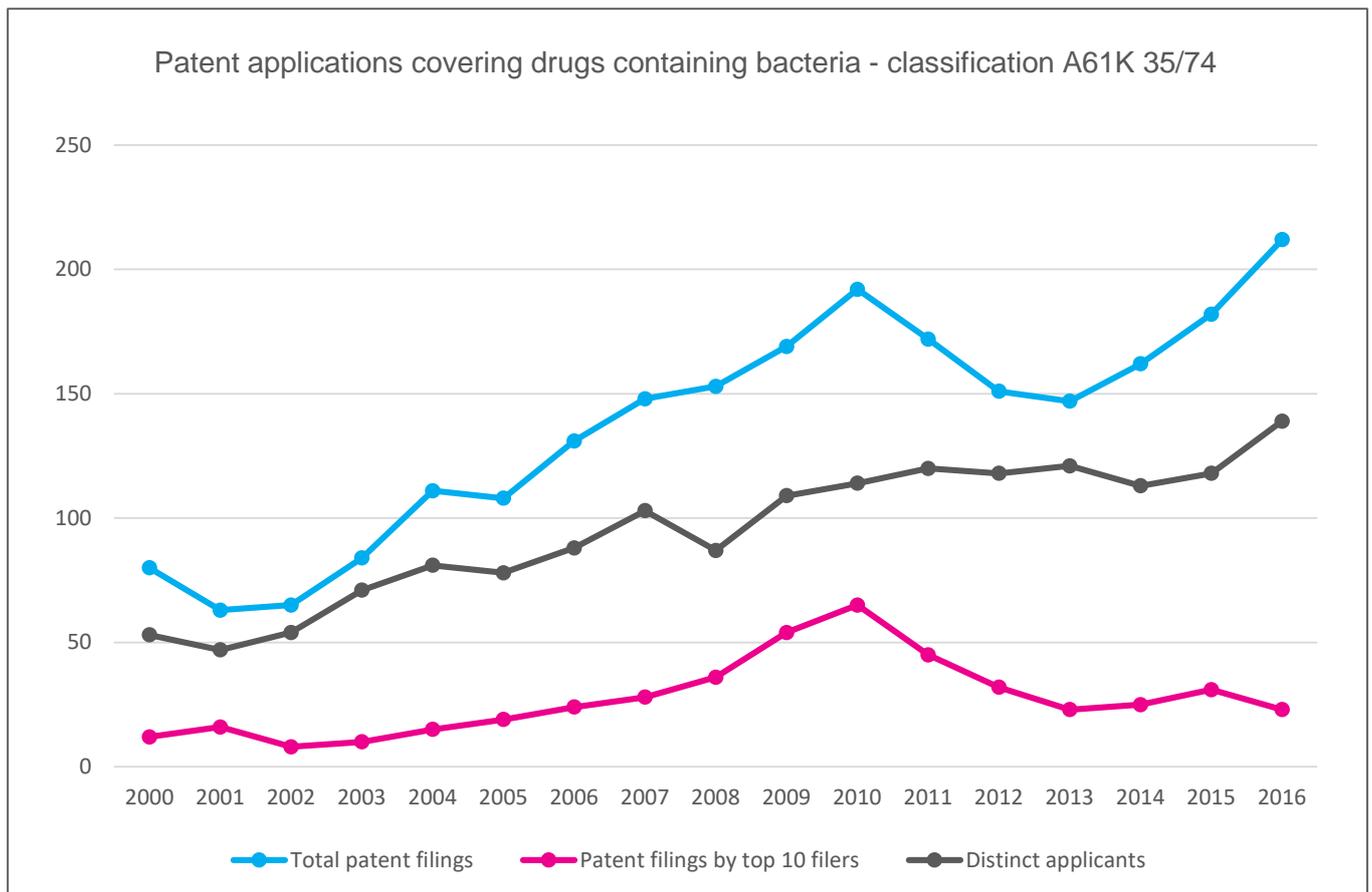




Patenting inventions in the microbiome: opportunities and challenges

As 10 years of focussed research into the microbiome bears fruit and more products progress closer to market, the importance of patents for protecting innovations and supporting further work continues to grow. Indeed, the recent rapid increase in the number of patent applications that are filed each year in the microbiome space and the striking increase in the number of different companies that are filing patent applications show that the progress being made in the microbiome sphere provides great opportunities for developing valuable patent portfolios, even if harnessing the power of bugs also presents patent applicants with particular challenges.

A simple search for patent applications covering medicinal products containing live bacteria, which is an area of microbiome research that happens to be easy to analyse using patent classifications, shows that filing activity has increased dramatically (see the graph below). This increase is particularly interesting considering that filing numbers in the biotechnology field as a whole have remained pretty stable over the past decade.





Further interesting insight can be found by looking at who is filing patent applications, and it's clear that much of the increase in filings described above is driven by new companies starting to build up patent portfolios, rather than increased filing activity from the more established companies. The graph overleaf shows that filings from the top 10 biggest filers since 2000 have actually reduced in recent years, whilst the number of different companies filing applications in this field is increasing.

The number of patent applications filed by relatively small companies reflects how important robust and comprehensive patent portfolios are for companies looking to attract investment. Even the most exciting science is going to struggle to persuade backers to commit in the absence of tangible IP assets; often, patent applications and trade secrets are all that a fledgling company possesses. Also, with more companies trying to carve out niches in what is a competitive market, patents can be a very useful tool for generating some exclusive space.

When developing a patent portfolio it's important to appreciate the full range of different developments that can be protected, and that's particularly true for therapeutic products. In order to incentivise the development of new therapies using known drugs, most patent systems around the world offer protection for various different types of new medical uses, and this is especially useful for researchers developing therapeutics using known products from the microbiome because it means that patents can be used to protect the use of known products for treating new diseases. It's also possible to obtain patents even when the same active agent is already known for treating the same disease, and the European Patent Office routinely grants patents directed to new modes of administration, new patient sub-groups and new dosage regimens.

Therefore, following initial patent filings covering new active agents, or when using known products, innovators and their patent attorneys should be constantly looking out for new opportunities to draft patent applications directed to any such developments that could provide new medical use claims and further patent filings.

It is not only in the field of medicinal products that patent systems offers diverse ways of protecting an invention. For example, although many patent systems appear on their face not to offer patents for new computer programs, algorithms or diagnostic methods, it is in fact possible to protect such developments using a range of different claim types.

Indeed, the European Patent Convention allows for significant flexibility in claiming diagnostic methods and new products and kits for use in such methods. It is also possible to claim methods, systems and hardware based on new computer programs and algorithms, as long as a tangible technical effect is achieved.

Despite the opportunities outlined above, there are also challenges faced by patent applicants in the microbiome space. In particular, as the field is relatively new, many patent examiners have little experience of claims that refer to bacteria and there are very few examples of cases that have been tested in the courts to provide guiding case law. This is in contrast to, for example, monoclonal antibodies, where it is now well established what scope of claim an applicant can expect after developing particular new antibodies. As a result, developing patent portfolios in the microbiome space is complicated by a lack of predictability that demands detailed planning and a flexible approach.



A significant challenge faced by all innovators is deciding when to file a patent application and when to wait until more supporting data are available, and this is especially difficult working with the microbiome, because it is a new field and there is increased uncertainty about what sort of data are required to show convincingly that something is actually likely to work therapeutically. Looking across to better developed areas with which the patent offices are more familiar, identifying new antigens in the vaccine field using *in silico* data is unlikely to be enough to justify the grant of a patent, but data showing that neutralising antibodies can be elicited in animal studies may be enough. On the other hand, in the antisense oligonucleotide field, it is now often necessary to show an effect on clinical symptoms in an animal disease model in order to obtain patent protection. It is harder to make such statements in the microbiome field, so innovators using the microbiome will need to carefully assess the technology already available and the strength of their models and data, and how long it is possible to keep their development secret, before settling on a robust filing strategy.

Another concern in the microbiome space is the recent hardening of practice at the US patent office regarding patent applications claiming naturally-occurring products, such as bacteria, and methods based on natural phenomena, such as diagnostic methods, which risk being deemed ineligible for patent protection. However, this challenge should not present a significant obstacle to developing patent portfolios, and from those, a business presence in the US.

Again, this challenge also rewards creative patent drafting and close collaboration between patent attorneys, commercial and technical teams. Indeed, there are few objections raised by the US patent office that cannot be circumvented with creative claim amendments and tailored arguments, and if these claim amendments are closely aligned with the commercial and technical needs of the business, then useful patent protection is still available in the US.



Ian MacLeod
Senior Associate
ian.macleod@carpmaels.com

Carpmaels & Ransford LLP is a leading firm of European patent attorneys based in London. For more information about our firm and our practice, please visit our website at: www.carpmaels.com.

This information provides a summary of the subject matter only. It should not be acted on without first seeking professional advice.

Carpmaels & Ransford LLP is regulated by the Intellectual Property Regulation Board (IPREG).

Copyright © Carpmaels & Ransford LLP 2017