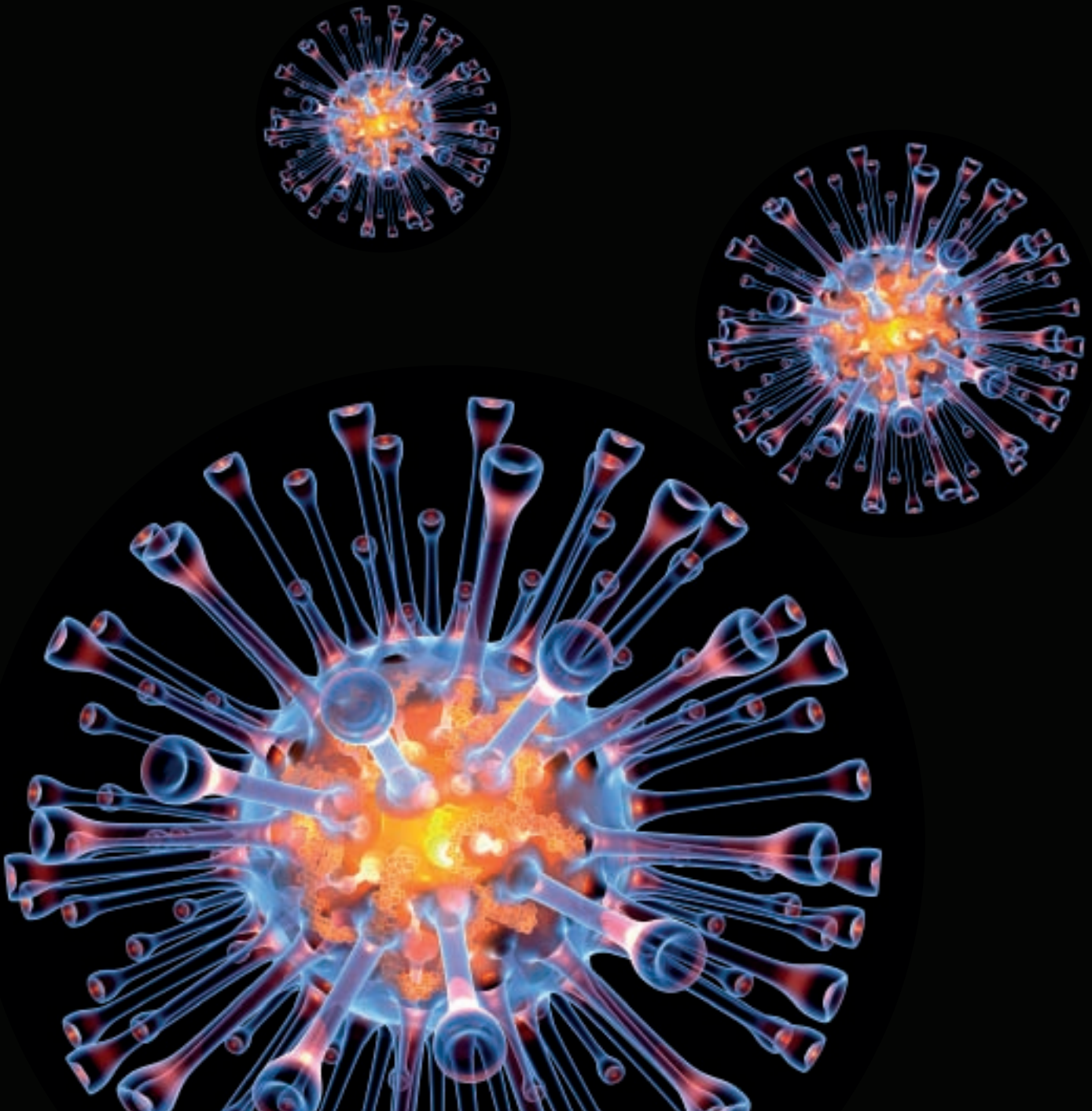


Life Sciences Report 2013

An executive summary

The changing IP landscape



A shifting regulatory landscape provides the backdrop to this year's Marks & Clerk Life Sciences Report. With fundamental changes taking place to the IP regimes of key markets, the life sciences industry has to accommodate and plan for different ways to protect its key assets.

Our 2013 report offers expert insight, backed by industry opinion, on this changing regulatory landscape, with a focus on the impact of the America Invents Act and the European Unitary Patent and the Unified Patent Court on the life sciences sector; the issues the sector faces in getting its therapies to patients, looking specifically at those associated with biosimilars, SPCs and personalised medicine, including stem cell research; and a look at the increasing importance of Asia.

We would like to thank the 338 life sciences representatives from across the world that participated in our detailed industry survey. The opinions they expressed were invaluable in our analysis of the challenges facing the sector.

With only one in five respondents to our survey stating that the overall financial climate across the Life Sciences sector has improved over the last twelve months, and almost nine in ten deeming the the global economic climate to be a very significant or quite significant factor for the life sciences sector over the next five years, the global industry continues to experience the effects of the last five years' economic events.

Against this hazardous backdrop, we have seen an increased interest in non-core business activities as a means for dealing with current challenges: half of all respondents believe that the appetite for partnerships and strategic alliances has improved in the last twelve months, and over a third feel the same about mergers and acquisitions.

Of particular concern to the European life sciences industry will be the ascendancy of China, as it and the US race ahead of Europe in terms of commercial attractiveness. That said, the regulatory regimes in the growing Asian markets still have some way to go, with the US and Europe maintaining their positions as the most attractive markets in terms of regulation, and China and India scoring the lowest.

The changing regulatory landscape

The parallel reforms of the European and US patent systems taking place with the implementation of the America Invents Act and the creation of the Unitary Patent and Unified Patent Court are transforming the two continents' IP systems, and, in some respects, bringing them closer together.

America Invents Act

With a move from the first-to-invent system to first-inventor-to-file and the introduction of new post-grant validity challenges and expedited examination, all of which bear similarity to procedures at the European Patent Office, the America Invents Act has brought about the first substantive amendment to US patent law since 1952.

The industry's reaction to the changes brought about by the Act is somewhat mixed, with 47 per cent of respondents considering the changes positive for the US life sciences industry and only 28 per cent feeling the same for European life sciences companies.

The Unitary Patent and the Unified Patent Court

The last year has seen unprecedented progress towards a single patent system for the EU. After decades of negotiations, the Unitary Patent and Unified Patent Court system have been agreed by all but two EU member states. Further steps, however, still need to be taken for the systems to come into force, including the ratification of the Agreement on a Unified Patent Court by each signatory state.

Despite the lead held by the US over Europe in terms of market opportunities and regulatory regime, participants in our survey are more enthusiastic about the European patent reforms than they are about those on the other side of the Atlantic. Over two thirds feel the changes in Europe will go some way to addressing the historical problem of a fragmented marketplace.

Under the new European system, London will be a key location for the life sciences industry, as it hosts the central division of the court allocated all cases concerning "chemistry, metallurgy and human necessities", which encompasses all life sciences products (small molecule and biologics), medical devices and other associated equipment.

Getting therapies to the patient

Biosimilars

Considering the concern from biotech and pharma companies about the threat of biosimilars to existing biologic therapeutic products, our survey highlights that there is generally very little awareness of the status of biosimilars, with 70 per cent of respondents unaware that two biosimilar monoclonal antibody products are currently being evaluated by the EMA for regulatory approval in Europe.

Despite the lack of awareness within the industry, nearly two thirds of survey participants expect the predicted rise of biosimilar monoclonal antibody products to be significant for the commercial landscape of the life sciences industry. With 84 per cent stating that it is important to the life sciences industry that regulatory regimes establish clarity with regard to biosimilars, there is a clear call to action for policymakers to act in this increasingly important area.

SPCs

The European system for patent term extension – SPCs, or Supplementary Protection Certificates – which is heavily used by the life sciences industry, has, over recent years, developed in its complexity and opacity. Thanks to seemingly contradictory case law from the Court of Justice of the European Union (CJEU), inconsistency in the manner in which different EU member states apply SPC-related rulings remains. Indeed, the frustration of national courts with the CJEU is becoming apparent from recent developments.

Only one in five survey participants believe the current SPC system is fit for purpose, and with more than half believing that dwindling pipelines will increase the reliance of the life sciences sector on SPCs going forward, it remains to be seen how Europe can best respond to the sector's evolving needs.

Personalised medicine and stem cells

Uncertainty surrounds the patentability of the various strands of personalised medicine, which is proving to be one of the most exciting and fast-developing fields in the life sciences. There is real divergence between the US and European positions on key areas such as isolated DNA and biomarkers, in particular thanks to recent case law coming out of the US.

Stem cell technology is an extremely politicised area of life sciences research. The recent CJEU Brüstle decision which excludes from patentability stem cell lines that were created involving the destruction of human embryos will, according to the majority of survey respondents, have a negative impact on levels of research and investment in the stem cell community, with 29 per cent stating they believe it will lead to R&D relocating away from Europe.

The competitive landscape

The clear excitement felt by the global life sciences industry regarding the opportunities presented by Asian markets, particularly China, will be accompanied by continued increased investment in the region, according to our survey participants: 84 per cent expect the life sciences sector to increase marketing, sales and advertising investment in Asia over the next five years, 80 per cent expect an increase in investment in

production capability and 69 per cent expect an increase in investment in R&D capability.

Despite the significant increases in patent and other IP filings in China over the last five years, the amount of Chinese-originating IP filed abroad is quite low, as analysis of statistics from the World Intellectual Property Organization demonstrates. Although 66 per cent of survey respondents believe that the rise of China will fundamentally transform the global life sciences industry, no associated wave of Chinese-originating IP filings overseas has yet materialised.

The Focus on Asia section of the report is accompanied by territorial updates on the IP regimes in various Asian countries and Australia, including sections on:

- Singapore's positive grant system
- Hong Kong's provisions for data exclusivity and its patent system reform
- Australia's landmark decision on the patenting of isolated genes and its Raising the Bar Act
- Thailand's tightening of pharma patent requirements
- India's first compulsory license upheld, together with the second filing of an application for a compulsory license; its Supreme Court's rejection of Novartis' Gleevec/Glivec patent; its treatment of Statements of Working; changes to its patent attorney qualification system; and the publication of the final version of its biotechnology patent guidelines
- Indonesia's decision to override patents on seven HIV and hepatitis treatments, to open the way for cheap generic versions of those drugs

For more information and a copy of the full research report, contact your usual Marks & Clerk attorney or solicitor, or one of the report authors overleaf.

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