The life sciences industry: trends and predictions

www.practicallaw.com/0-501-0094

Aditi Mene, PLC Cross-border

MAJOR DEVELOPMENTS FOR A GLOBAL INDUSTRY

The life sciences industry has experienced major changes over the last few years, and will continue to be affected by a number of technological, commercial and legal developments in the coming years. In all the major life sciences manufacturing and research hubs, change has been underway in terms of:

- Market and regulatory changes.
- The effect of the economic climate, which has propelled competition, consolidation and diversification of pharmaceutical companies.
- Increased litigation.
- Patent expiries.
- Funding issues.

The pharmaceutical industry is also part of a globalised market, where very few companies can remain purely local in their outlook and reach.

This article examines the changes that have occurred in the key life sciences jurisdictions of Europe, the US and China, and considers lawyers' predictions for the future of these local and international markets.

THE EUROPEAN LIFE SCIENCES INDUSTRY

The European life sciences sector has seen a number of significant changes occur in the past year, including:

- A European Commission (Commission) sector inquiry into the lack of competition in the pharmaceuticals industry, including companies finding new ways to extend their patents, a possible unified patent system and European Patent Court, and a potentially streamlined European regulatory system.
- A stricter regulatory landscape.
- Issues caused by the economic crisis, such as consolidation and partnering.
- Funding problems.
- Involvement in emerging markets.

The Commission's sector inquiry

As a result of a European market dominated by large innovator pharmaceutical companies, and generics increasingly edged out, the Commission launched an inquiry in 2008 to look into these issues. Its focus was to examine the state of the market and consider the barriers to entry preventing generics from entering the market, as well as to look at the competition that was occurring between innovator companies.

The inquiry's main findings were published in July 2009, and concluded that:

- Competition does not work as well as it should in the pharmaceutical industry.
- There is a delay in generics entering the market.
- The reasons for these issues are because fewer of the innovative drug companies are creating new medicines, and they are therefore using a number of different techniques to delay generic entry into the markets and to hold on to their expiring patented drugs for as long as possible.

Some of the inquiry's non-binding recommendations were:

- To bring more anti-trust actions against innovator companies using delaying and anti-competitive measures such as:
  - defensive patenting strategies;
  - establishing settlement agreements with generic companies that affect consumer choice.
- To improve and streamline the regulatory framework in relation to the marketing authorisation process and pricing and reimbursement provisions.
- To reach an agreement on a Community Patent and patent litigation system.

Lawyers have mixed reactions to the sector inquiry, and are either alarmed at the interventionist stance the EC has taken, or are approaching it with a wait-and-see attitude.

Laura Anderson from UK firm *Bristows*, comments that the inquiry has been "troubling" for clients, because up until recently, pharmaceutical companies had become accustomed to the competition authorities and the EC leaving them alone. Pat Treacy, also from *Bristows*, notes that the competition authorities only ever used to get involved in relation to mergers and parallel trade; but "their involvement regarding other behaviour had not been notable". Both Treacy and Anderson think that the inquiry has been "traumatic for the industry", particularly in its scrutiny of companies' management and defence of their IP rights and assets. Treacy notes that some of her clients have been asking for risk analyses and have been concerned about the potential legal consequences of the inquiry.

© This document was first published in the PLC Cross-border Life Sciences Handbook 2009/10 and is reproduced with the kind permission of the publisher, Practical Law Company. For further information or to obtain copies please contact antony.dine@practicallaw.com, or visit www.practicallaw.com/lifescienceshandbook.

Both partners agree that it is still too early to say what the effect of the inquiry might be on market behaviour and, in legal terms, it is unclear what might happen next. Treacy is not certain whether patent litigation will be affected. She reports that some companies, as a matter of policy, are making long-term and sophisticated plans to protect and enforce their legitimate rights, which is a reflection of the fact that "their products are so valuable and shareholders need their returns". Anderson thinks, however, that "commercial arrangements between competitors might be affected, as there is a heightened level of anxiety with more risk-averse behaviours occurring".

Malcolm Bates from UK firm *Taylor Wessing* has another view of the inquiry, and says he "would be surprised if the Commission is aggressive" in pursuing patentees as, up until this point, it has been "very anodyne" in relation to this. He thinks that the focus of the Commission will primarily be on settlements between innovator and generic companies. In recent times, he has seen this focus resulting in "dawn raids" on a number of pharmaceutical companies. Meanwhile, Peter Bogaert from *Covington and Burling*'s Brussels office thinks that the inquiry is also a reflection of the past five years, "which saw a trend for regulators wanting to have a say in how drugs are managed".

The European Patent Court. The inquiry's discussion of a streamlined Community Patent and European Patent litigation system attracted more uniform responses from lawyers. Pat Treacy notices that the drive towards the Community Patent has taken on considerable momentum. She also comments that the European Court of Justice has been restructured in the Lisbon Treaty to leave some room for a European Patent Court within it. She does note, however, that there is still some scepticism about when this court will actually come into existence and how it will operate. When it does, it will prompt a number of questions from the pharmaceutical industry, which is one of the biggest filers of patents. Treacy also thinks that the eventual adoption of a Community Patent will require companies to think about whether they need to change their filing strategies, as many may wish to keep individual filings in each member state, rather than filing just once.

Malcolm Bates agrees that the steps towards a European patent are happening rapidly, and that most pharmaceutical companies are anticipating these developments. However, he notes that lawyers will be concerned about the quality of any unified patent litigation procedure, which he considers should provide companies with "an opportunity for evidence and witnesses to be examined in the style of the current system in the UK. This is in contrast to the more limited way that some other European jurisdictions deal with this". He notes that, despite national sensitivities, all member states will need to adapt and accept the changes that might occur to their own patent systems.

The European Patent Court idea also highlights the tensions between patent attorneys and patent lawyers and what their respective roles might be. Commentators note that there is already a political standoff between patent attorneys and patent lawyers, with patent attorneys keen to have their rights of audience in all patent courts. However, patent lawyers argue that the problem with this is that patent attorneys do not have much experience of infringement actions, or dealing with witnesses and evidence. The streamlined European Patent Court would have to deal with the variety of problems that are occurring between the two professions.

The common framework agreed for the unified patent litigation jurisdiction still needs to be approved as "legal" by the European Court of Justice. After this, all interested parties will need to decide the details of the procedure for the European Patent Court. Key issues to decide include the composition of the judicial panels, the language of proceedings, and the extent of the ECJ's role.

Kristina Nordlander from *Sidley Austin* in Brussels also comments that everyone seems to agree that a Community patent court is necessary, and that "interestingly the push is more for a Community judiciary than a Community patent".

Streamlining the regulatory framework. Within the inquiry, there was also discussion of streamlining the regulatory framework for marketing authorisation and national pricing and reimbursement for pharmaceuticals in Europe. Stakeholders contributing to the inquiry pointed out that the regulatory framework and the network of member states' authorities needed to be more efficient and less burdensome in terms of administration.

Pat Treacy mentions that the European pharmaceuticals industry is one of the most heavily regulated industries in the world, but that certain regulatory issues differ between member states. She notes that suggestions have been discussed within the inquiry to make the regulatory process more streamlined and to allow for better harmonisation across Europe. However, the inquiry stated clearly that it did not intend to analyse the regulatory issues in detail.

Some lawyers comment that the discussion about streamlining the regulatory process has been ongoing for a number of years, but that very little had occurred despite the discussions. They were sceptical that any notable reform would happen immediately. Kristina Nordlander also points out that while the sector inquiry indicates that there is the need for a streamlined regulatory framework, it cannot provide any clear guidance on this issue in the context of the competition rules. She notes that despite the enormous push for regulatory harmonisation, there is likely to be enormous resistance due to national sensitivities in each member state relating to public health systems and the financing of medicines. It may not be possible to overcome political resistance in the short to medium term.

However, Malcolm Bates comments that the introduction of the decentralised procedure, and the greater number of applications now being processed through the European Medicines Agency (EMEA), is resulting in faster, broader access to products for patients. Additionally, he notes that, in the UK, initiatives such as the Innovation Pass regime remain important in encouraging the use of innovative new treatments where appropriate. He also adds that the National Institute for Clinical Effectiveness (NICE) is at the forefront of other such initiatives, for example, the establishment of the Medical Technologies Advisory Committee to speed up the use of medical devices and diagnostics within the NHS.

A stricter regulatory landscape

Grant Castle from *Covington and Burling*'s London office notes that the general enforcement environment in Europe has become stricter in the past few years. He mentions that the US Food and Drug Administration (FDA)'s stance has traditionally been much more aggressive than most of the regulators in Europe, but he predicts that this will change and, like in the US, there will be a greater focus on enforcement and penalties on pharmaceutical companies.

© This document was first published in the PLC Cross-border Life Sciences Handbook 2009/10 and is reproduced with the kind permission of the publisher, Practical Law Company. For further information or to obtain copies please contact antony.dine@practicallaw.com, or visit www.practicallaw.com/lifescienceshandbook.

As examples, he cites the EC's 2007 Penalties Regulation, which allows the European Commission to impose heavy financial penalties for breaching marketing authorisation regulations. National bodies such as the UK's Medicines and Healthcare Products Regulatory Agency (MHRA), are also likely to follow suit by exercising enforcement powers more stringently. Castle sees regulators scrutinising companies and hoping to make examples of those that have breached regulations, particularly where this has resulted in a risk to the public health. Maurits Lugard from *Sidley Austin* in Brussels agrees, noting that "the EC seems very interested in using the Penalties Regulation as a tool to give the EMEA leverage over the industry". The penalties can be enormous: up to 5% of the company's turnover in the EU in the preceding business year. However, as Lugard notes, the text of the law is unclear whether this is the EU turnover of the drug in question, or of the company's total EU turnover.

Castle also points out that regulators are becoming much more pro-active in their management of risks associated with medicines. There are moves to streamline and simplify the process through which the EMEA's scientific advisory body, the Committee for Medicinal Products for Human Use (CHMP), acts against products. Castle notes that there are also moves to formalise an ad hoc system that the EMEA's Pharmacovigilance Working Party has operated for some time, without any real procedures or mandate. He mentions that one of the new features of the stricter regulatory landscape is that laws are now being amended to allow regulators to take action on a precautionary basis, or whenever they perceive a risk, rather than waiting for the risk to be established or quantified. The consequences of this, Castle notes, is that research and development (R&D) is much more vulnerable and must be carried out with more caution than before.

He also predicts that in the future, pharmaceuticals companies will have to contend with a much heavier regulatory burden. He thinks that it is highly likely that companies will need to have more elaborate systems in place to cope with this added regulatory pressure, and will need to prove the value of their products and show how they work for the patients. In fact, Bogaert and Lugard both think that the EC's recent moving of the pharmaceutical industry body (Unit F2) from the Directorate-General for Enterprise and Industry to the Directorate-General for Health and Consumers signifies a shift away from defending the rights of the industry in Europe towards a more patient-focused outlook.

The global financial crisis: consolidation and partnering

The global financial crisis has had a marked effect on the life sciences industry. According to Daniel Pavin from *Covington and Burling*'s London office, the crisis "has affected the way in which pharmaceutical companies address risks associated with a partner who might be suffering from financial instability". This means that the way in which companies do deals has become more cautious and risk-averse. He notes that some companies are now including enhanced protections and securities within their contracts with partners, and some are even deciding against entering into licensing deals because of the risk that the licensor may become insolvent. Instead, Pavin notes, the pharmaceutical company may opt to buy the licensor instead. He mentions that there are "numerous stories of small to medium companies being picked off in this fashion".

Laura Anderson echoes this and notes that in the face of the economic crisis, a number of smaller companies within the life sciences industry have struggled, with some even collapsing or selling off their assets. She mentions that a number of smaller companies have held fire sales where their assets were picked off separately. She predicts that this will continue into 2010, where stronger companies will be looking for bargains. Malcolm Bates agrees, and comments that many biotech companies have been jockeying for position and looking for cash-rich companies to merge with. However, he points out that this is not without its problems, with many potential deals breaking down over valuations and management roles within the merged company.

Anderson also observes that other than major deals at the top end of the market, M&A has generally been down in the past year, but strategic alliances and collaborations have been occurring instead. Anderson notes that licensing and collaboration deals remain an attractive way for pharmaceutical companies to build their R&D pipeline. She also cites a number of recent deals she has worked on in this area. One recent project involved a Norwegian company, Algeta ASA, which has developed a new product for cancer treatment which was is in Phase III clinical trials. It needed a partner to take the product forward, so it entered into a lucrative deal with Bayer. Another of Anderson's projects involved University College London (UCL), which is developing a new stem cell therapy in collaboration with Pfizer. The development of this therapy is now a lead regenerative medicine programme for Pfizer. Anderson comments that many companies are looking for these sorts of projects, "where they can get external expertise in new areas or strong product candidates".

Pavin also notes that the increasing pressure for companies to fill their R&D pipelines has also pushed them to consolidate within the sector. He predicts that the trend for consolidation with competitors, which started within the past five years, will be continuing into the future and for as long as companies are known to be "only as good as their last drug". This consolidation includes not only mergers between innovator pharmaceutical companies, but also between innovator and generics companies. For example, GlaxoSmithKline made a number of acquisitions of generic companies from Asia and South Africa in recent years, as did Sanofi-Aventis.

Malcolm Bates also points out that many innovator companies have their own generics divisions (such as Swiss pharmaceutical company Novartis and its generics arm Sandoz), and that some of the major generics companies are also starting to get involved in drug development and acquisitions (such as Israeli generics company Teva). He predicts that eventually the lines between innovators and generics will become blurred. Pat Treacy agrees, stating that the age-old distinction between generics and innovators will change, as the industry continues to evolve. She notes that, already, there are some generic companies that have developed into large, sophisticated companies while a number of innovators have significant generic operations. The rise of generics and branded generics in China and India has also no doubt contributed to this shift in the market (*see below, Involvement in emerging markets*). Malcolm Bates speculates that as generics and innovators become more alike, the amount of litigation between the two types of company could perhaps decrease, although he notes that he has "not seen any drop-off in litigation activity in either the UK or Germany where the firm has life sciences practices".

© This document was first published in the PLC Cross-border Life Sciences Handbook 2009/10 and is reproduced with the kind permission of the publisher, Practical Law Company. For further information or to obtain copies please contact antony.dine@practicallaw.com, or visit www.practicallaw.com/lifescienceshandbook.

Bates also notes that biotech companies are playing an increasingly important role in the life sciences M&A market, with more pharmaceutical companies attempting to buy into the biologics sphere. He thinks that the success of big pharmaceutical companies such as Roche, Genetech, AstraZeneca and GlaxoSmithKlein buying into the biologics market has propelled other pharmaceutical companies into the biotech field. Bates notes that this trend looks set to continue because of the high margins such products can command and the greater difficulties for generics companies to break into the market on patent expiry. Richard Kingham from *Covington and Burling*'s London office agrees, noting that biotech companies are reshaping themselves, in order to attract more research-based pharmaceutical companies to get involved with them.

Anderson adds that certain large pharmaceutical companies are still trying to build a more diversified offering, which might include devices, generic arms and consumer products. Kingham also notes that diversification is a particularly popular trend at the moment, but is not sure whether it will be permanent, as he has seen a number of companies divesting themselves of their medical device or generics arms a few years after obtaining them. The only major truly diversified company remains Johnson and Johnson.

The lawyers make a number of potential predictions for the future of a consolidated life sciences sector. Peter Bogaert thinks that pharmaceuticals companies will have increased contact with other companies selling different products and services, and more patient-specific medicines and integrated solutions will begin to be developed as a result. Malcolm Bates agrees, seeing pharmaceutical companies moving into areas such as gene therapy, which were once considered high risk in terms of development. One example of this is Sanofi-Aventis' recent deal with Oxford BioMedica, in respect of its Lentivector technology for ocular disorders. Bates thinks that most pharmaceutical companies will want at least some exposure to such therapies as "insurance against the future".

Funding issues

The rise of diversification has also occurred as a result of funding difficulties. Malcolm Bates notes that it has been much harder for biotech companies to raise money over the past year. He states that venture capital funds and early stage seed funds are finding it hard to raise capital, so "fewer funds are having money to invest in biotech and pharmaceutical companies". However, those that are investing are tending to concentrate on later stage opportunities, rather than companies in the early stages of traditional drug discovery and development.

Bates notes that some early-stage companies are still managing to obtain some funding from corporate venture capital funds, or through a syndicate of those and traditional venture capital funds. He cites the recent successful example of Heptares Therapeutics, which raised a sizable sum earlier in February 2009, with a third of the money coming from Novartis Option Fund (part of Novartis Venture Funds) and the remainder from two sizable venture capital funds, MVM Life Sciences Partners and Clarus Ventures. This was followed up in October 2009, with an amendment to the deal and Novartis entering into an option agreement with Heptares, worth US$200 million (about EUR137 million), to produce new drugs for various diseases. Bates notes another interesting example of this type of investment occurred again in October 2009, where a new biotechnology company, Bicycle Therapeutics Ltd, obtained seed funding from Novartis Venture Fund and Atlas Venture. Bates notes that Bicycle Therapeutics is a spin-off company based on the work of the Medical Research Council Laboratory of Molecular Biology in Cambridge, and is still essentially in the very early stages of being established.

Bates comments that these examples are an indication of where the venture capital money will be coming from, and where it will be going in the future. He predicts that in the medium-term these sorts of deals will occur more, and will be the only way some companies will obtain funding. However, he notes that "although pharmaceutical companies are suffering, the balance of power is moving back to them, as they have deeper pockets compared to most other companies".

Involvement in emerging markets

Daniel Pavin points out that one of the other trends that has affected the life sciences industry is one that has been seen in other industry sectors: the growing opportunities in emerging markets, including Brazil, India and China (the BRIC countries). Originally, he explains, the primary reason for entering these markets was for outsourcing purposes and to reduce costs. He notes that, for example, India has for some years been a country to which manufacturing has been outsourced, with highly-skilled chemists and biologists locally employed. However, Pavin explains that the markets are now about more than just making use of the labour, but also about the growing affluence of emerging market populations and the increasing market demand for branded generics and vaccines. He comments that, to Western pharmaceutical companies, these BRIC countries "now represent attractive markets for new sales and developing new types of products and marketing".

However, once innovator companies lose their patents, they are starting to experience intense competition from generic drug companies in these markets. This has prompted some European innovator pharmaceutical companies to branch out into branded generic drugs once the patent on their drug has expired, which saves them some lost revenue. Some large innovator pharmaceutical companies such as GlaxoSmithKline have even acquired local generics arms to produce branded generics in these countries. The company Pfizer also announced in May 2009 that it would be doing licensing deals with Indian generics companies.

THE US LIFE SCIENCES INDUSTRY

The US life sciences market is the biggest in the world, and the past few years have seen a number of major developments. While a number of trends are similar to those occurring in Europe, US lawyers and life sciences companies also have very specific concerns relating to, among other things:

- Healthcare reform legislation, including the enactment of biosimilars legislation.
- Increased regulatory pressures.
- Consolidation within the industry.
- The economic stimulus package and its effect on the industry.
- Increasing competition from emerging markets.

© This document was first published in the PLC Cross-border Life Sciences Handbook 2009/10 and is reproduced with the kind permission of the publisher, Practical Law Company. For further information or to obtain copies please contact antony.dine@practicallaw.com, or visit www.practicallaw.com/lifescienceshandbook.

Healthcare reform legislation

The likely enactment of healthcare reform legislation will impact hugely on the life sciences industry in the US. Stephen Paul Mahinka from *Morgan Lewis* in Washington, DC explains that if the legislation goes ahead, it will mean that 30 million more people will have health insurance which will result in an increased demand for drugs, devices and other medical assistance. As a result of this, Mahinka predicts that there will be an increased focus on the cost effectiveness of drugs, as well as an increase in fraud and abuse investigations. He notes that there will undoubtedly be more regulatory work, and a possible increase in transactional work with more consolidations taking place between healthcare companies.

Mark Lynch and Peter Safir from *Covington and Burling*'s DC office agree that the healthcare legislation will be important, but are uncertain as to how it will actually impact on the life sciences industry, as it may be subject to a number of changes before it is actually enacted. However, they concur that because of increased insurance, more people will have access to medical services and be able to afford more medicines. They think that "depending on the terms of coverage, this could be a good thing for the pharmaceutical industry".

Cost controls. However, some in the media and pharmaceutical industry have raised concerns about the inevitable cost controls that will come with healthcare reform, and the way they could hinder the development of new blockbuster drugs (with R&D traditionally being the most expensive area for pharmaceutical companies). The counter argument that some have put forward to this is that price caps would not necessarily impede the development of new drugs, because the drugs market is global and therefore the drugs could be exported to other countries. However, the concern still remains that the US is a major market, and one of the biggest consumers of drugs, so if price controls and cost-benefit analyses do depress companies' R&D budgets, there could be a problem for the profit-making abilities of US life sciences companies.

Despite this, some pharmaceutical companies are thinking of ways to avoid these problems by following the examples of companies selling drugs in countries such as the UK, where cost-benefit analyses and comparative reviews of effectiveness already take place. Some companies have started offering financial guarantees if their drugs do not work as well as they claim. It remains to be seen how the US pharmaceutical lobby will react if such cost controls are eventually put in place as a result of the legislation.

Biosimilars legislation. Related to the healthcare reform legislation is possible legislation creating an approval pathway for biosimilars or generic biologic drugs. Mahinka notes that this could have a major impact on transactional work for biotech companies, increasing the difficulty of valuation of targets. He also thinks that litigation work in relation to the approval of biosimilars of biotech products will also arise. Safir also notes that this legislation might prompt a "sea-change in the life sciences industry, with research-based drugs companies entering the follow-on biologics sphere". He comments that some innovative research-based companies are already moving into the biologic market. Lynch notes that the biologics bill is likely to herald lots of patent litigation in five to ten years' time, as has been the case with the 1984 Hatch Waxman Act patent legislation for pharmaceuticals.

Increased regulatory enforcement

As in Europe, US life sciences lawyers are concerned about the increasingly strict regulatory landscape. Mahinka points out that regulatory agencies such as the FDA and the Federal Trade Commission (FTC) have stepped up their enforcement activity, which is resulting in a much heavier regulatory burden for companies working within the industry.

Safir says that there has been increased enforcement activity for marketing and promotional programmes. He notes that these areas have become criminalised, "whereas six or seven years ago, these activities would have been enforced through civil means". He thinks the reason for the change in attitude is because authorities have noticed that enforcement actions and settlements are "where the money is" because the settlements that have been reached have been "huge".

As a result, pharmaceutical companies are focusing on compliance programmes to try to avoid costly litigation and settlement costs. Safir comments that many companies are also taking account of these potential enforcement and litigation costs within their budgets. Lynch also states that these criminal enforcements are having "a ripple effect, with State Attorney-Generals and class action lawyers also bringing more civil suits against drugs companies". It appears that an increasing number of large civil suits are being brought against pharmaceutical companies at a state level where, according to Lynch, "the dynamics are heavily weighted against the pharmaceutical company". He attributes this hostility to the industry being the result of each State needing more money and capitalising on an historical mistrust of large pharmaceutical companies.

In response, pharmaceutical companies are introducing standard operating procedures and chief compliance officers to deal with the increased regulatory burden. Lynch notes, however, that this has been a difficult process "because the pharmaceutical industry operates in a different way to other industries in the way in which its products are sold and marketed". He points out that the level of scrutiny on the marketing activities of the pharmaceutical industry is much higher than other businesses, and therefore companies need to be much more vigilant in an increasingly litigious environment.

Consolidation and diversification

As in Europe, US lawyers are seeing an increasing amount of consolidation between innovator and generic companies. There is also more partnership activity occurring between pharmaceutical companies and biotech and medical device companies. Despite the economic downturn, Lynch mentions that there "has seen a fair amount of deal activity and consolidation, but there is a limit to how much of this can continue".

As in Europe, it seems that the drivers for these consolidations are the lack of new blockbuster drugs in large innovators' pipelines, tighter cost margins, and increased competition from generic companies. However, although a few pharmaceutical companies are looking to join forces with medical device companies to broaden their lines or create combination products, commentators do not expect this trend to be widespread. Lawyers note that there is still a fairly strict division between pharmaceutical and medical device and biotech companies, but that the

© This document was first published in the PLC Cross-border Life Sciences Handbook 2009/10 and is reproduced with the kind permission of the publisher, Practical Law Company. For further information or to obtain copies please contact antony.dine@practicallaw.com, or visit www.practicallaw.com/lifescienceshandbook.

development of more personalised products and medicine could potentially work for both biotech and pharmaceutical companies in the future. Mahinka agrees, noting that the development of personalised medicines and devices in the future will affect the life sciences industry and prompt closer working between drugs companies and device manufacturers.

Mahinka remarks that traditional pharmaceutical companies will inevitably need to start broadening their strategies in order to survive in the more competitive environment. Mahinka suggests that in five years' time, the industry "will have a number of different companies with a wider variety of business models and strategies, and each with different structures". However, whether they diversify into generics divisions, nutritional products, OTC drugs, biotech or even biosimilars arms, nobody can yet tell what the most successful strategy or model will be.

The potential impact of the economic stimulus package

The US stimulus package, under the Health Information Technology for Economic and Clinical Health Act (the HITECH Act), has earmarked US$1.2 billion (about EUR820 million) for the development of healthcare technology across the US. This will lead to the current paper-based medical system becoming computer-based. Mahinka notes that as patient information and products and drugs services get transferred to electronic data storage, a number of opportunities will present themselves to information technology companies. This will also no doubt create privacy protection concerns, as well as other potential litigation issues. Mahinka states that any big change such as this will lead to a number of other developments as well, including regulatory changes and increased transactional work between information technology providers and others in the life sciences industry.

The stimulus package will also provide US$1.1 billion (about EUR750 million) for funding drug comparative effectiveness research, such as that in other countries including the UK (which has the National Institute for Clinical Effectiveness, NICE). Mahinka notes that the development of effectiveness measures for drugs and devices will certainly affect the scope of clinical trials, as well as the way in which drugs are marketed and priced through private insurers or through the government. He thinks that reactions to this potential development will probably result in litigation and substantial regulatory developments.

Work in emerging markets

Another key trend that is affecting the life sciences industry in the US is the rise of competition and opportunities from emerging markets such as China and India. As lawyers in Europe also note, manufacturing, clinical trials and R&D are becoming much more cost effective in India and China, as is the use of a local and highly skilled workforce. Peter Safir notes that, in these new growing markets, a number of the local generic companies will soon begin to compete with the Western companies, and start R&D work. As it currently stands, Mark Lynch explains that India and China are already playing a huge part in the generic pharmaceuticals industry, with research deals taking place in these countries. A growing number of US innovator pharmaceutical companies in emerging markets are also developing branded versions of their original drugs after they have lost their patents, and charging more money than the other generic competitors. Some innovators have also acquired generics competitors, which can help them move into branded generics more easily (as has also been the case for European companies, *see above, Involvement in emerging markets*).

This increased involvement in Asia and other emerging markets is likely to cause an increase in transactional work and regulatory issues, as well as an uptick in product liability and general commercial litigation, according to Stephen Paul Mahinka.

THE CHINESE LIFE SCIENCES INDUSTRY

The Chinese life sciences industry has experienced major growth in the past few years and, along with India, is playing an increasingly major role in the world's pharmaceutical market. Developments in the past few years include Western and other foreign pharmaceutical companies entering the market and using China as a manufacturing and R&D base, seizing the opportunities presented when the market was opened up. The government is also showing increased interest and providing funding to the industry.

Growth and foreign investment

The number of western and foreign companies which have set up offices and subsidiaries within China increased hugely following China's entry into the World Trade Organisation in 2001, and the lifting of investment and manufacturing restrictions. Shingo Hisata from *Morrison and Foerster*'s Tokyo office works for Japanese life sciences clients who are entering the Chinese market. He points out that the market's attraction lies in its sheer size and the fact that the Chinese economy is growing. A number of his Japanese clients have established, or purchased, Chinese manufacturing subsidiaries.

Hisata mentions that, besides foreign pharmaceutical companies, medical device and biotech companies are also having success in the country. So far, however, he has not seen any joint operations occurring between the pharmaceutical and biotech companies in the country (*see below, Future developments*). Hisata also earmarks a future trend for foreign companies undertaking clinical trials in the country. However, to do clinical trials in China, he states that the companies have to establish good relationships with local medical institutions before they can hope to enter this area. He is seeing more clients trying to establish consulting companies, or purchasing local consulting companies, in order to start these trials.

Tony Chen from *Jones Day* in Shanghai concurs with Hisata and says that he is seeing "a great deal of R&D work being conducted in China for large foreign pharmaceutical companies". He has seen many R&D centres being set up in the country, with European, US and local scientists. He also notes that many foreign companies have been sending contract research work to Chinese research companies, particularly in the areas of synthesis, biological assays and clinical and pre-clinical studies. He states that this type of contract research work has enabled a number of Chinese companies to grow; for example, Wuxi, which is listed on the New York Stock Exchange, and Shang Pharma, which may be listed in the near future.

Chen is also seeing a number of start-up drug discovery companies entering the market to conduct R&D work. He has seen a few of these companies established by scientists who used to work in Europe or the US, but who are now getting funding from the Chinese government. Chen reports that government funding for the life sciences industry, particularly for academic and other research institutions, has increased hugely in recent years. He notes that the government views the life sciences industry as particularly important for the health of the country, as well as for helping to deal with emergency situations such as SARS, H1N1 and other viruses.

© This document was first published in the PLC Cross-border Life Sciences Handbook 2009/10 and is reproduced with the kind permission of the publisher, Practical Law Company. For further information or to obtain copies please contact antony.dine@practicallaw.com, or visit www.practicallaw.com/lifescienceshandbook.

The effect of the global economic crisis has, according to Chen, been felt to some degree in China, but otherwise the life sciences market has remained stable. He remarks that some contract outsourcing activities have slowed a little, because R&D budgets had been cut. Despite this, he thinks that the market has been relatively secure because of the pressure on multinational pharmaceutical companies to cut R&D costs while maintaining productivity.

In fact, one of the main attractions for foreign companies entering China has traditionally been the cheap labour costs that are involved in the Chinese pharmaceutical industry. Hisata states that this is a major factor for many of his Japanese clients entering the market. However, he now notes that labour costs are beginning to increase substantially, since a new labour contract law was introduced two years ago. Although the cost is increasing, he still thinks that foreign life sciences companies will continue to use China's local workforce for as long as the companies continue to maintain a healthy profit margin, and for as long as they are still able to get good quality local staff. He also thinks that "for the time being, China is still seen as a major location for Japanese pharmaceutical companies because of the size of the market; the workable climate; the educated workers; and the shared alphabet, history and culture".

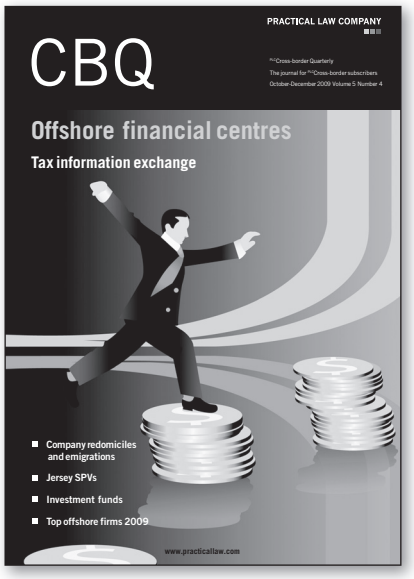
At the moment, it appears that most local Chinese pharmaceutical companies are not able to compete at the same level as foreign pharmaceutical companies operating within the market. However, both Hisata and Chen seem to agree that this could potentially change in the future (*see below, Future developments*).

Future developments

The number of Chinese generic companies branching out into R&D looks set to increase, according to Tony Chen. He notes that the line between innovative and generic development has already blurred for some Chinese generic companies. Jiangsu Hengrui, a generic drug company listed in Shanghai, and Simcere Pharmaceutical Group, which is listed in New York, are two examples that started as generic companies, but which have branched out into developing new drugs. Chen thinks that they are hoping to capitalise on the need for cheaper drugs in China. Hisata also notes that in five to ten years' time more Chinese companies will probably start to establish themselves, and that the local workforce currently working for Western companies may start to set up their own companies. Chen agrees, stating that in the next five years, "some Chinese company may finally come up with an innovative drug". He also thinks that the R&D work and foreign investment within China will begin to bear fruit with new drugs being established.

Although Hisata is not seeing the blurring that has occurred in the west between pharmaceutical and medical device companies, there is some indication that this will change in the future. Chen agrees and notes that he has seen some very successful Chinese biotech companies emerging in the past few years. For example, he cites Mindray, which is listed in New York, which "is doing very well selling medical devices in China, and is looking to grow", as an emerging competitor to Western biotech companies in the country. More competition from Chinese companies looks likely in the future.

PRACTICAL LAW COMPANY



PLC Cross-Border Quarterly
Paper publication

PLC Cross-border Quarterly is widely accepted as the most respected source of practical information and strategic analysis for lawyers working in a global environment. It provides market intelligence and legal know-how aimed at senior in-house counsel for multinationals, as well as partners in major law firms active internationally.

For more information please visit: www.practicallaw.com/crossborder

© This document was first published in the PLC Cross-border Life Sciences Handbook 2009/10 and is reproduced with the kind permission of the publisher, Practical Law Company. For further information or to obtain copies please contact antony.dine@practicallaw.com, or visit www.practicallaw.com/lifescienceshandbook.