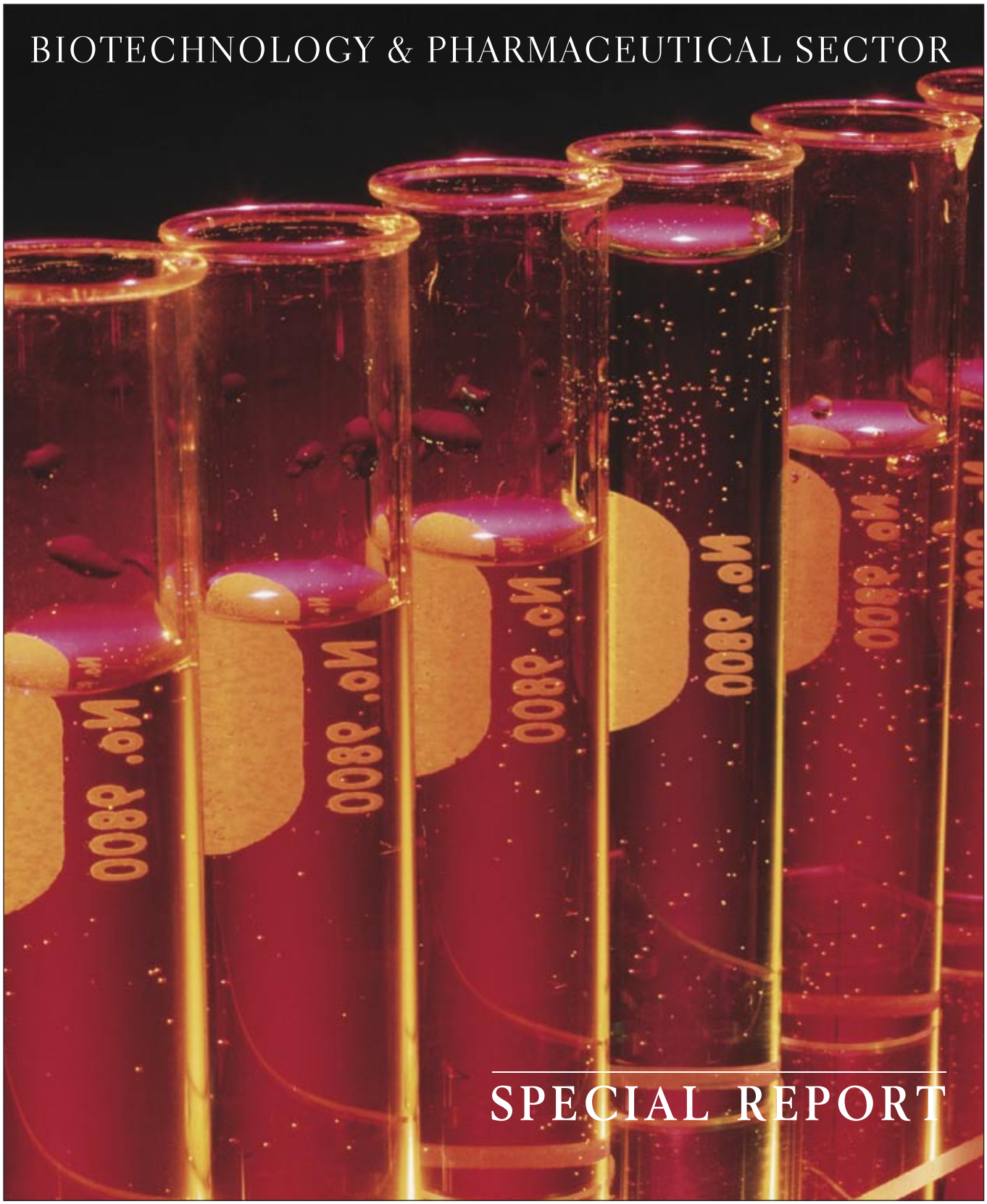
FINANCIER WORLDWIDE corporatefinanceintelligence

FEBRUARY ISSUE 2007 | REPRINT

BIOTECHNOLOGY & PHARMACEUTICAL SECTOR



SPECIAL REPORT

M&A and strategic collaboration

Biotech is one of the few sectors that seem to receive more attention for their failures than successes – for every Amgen or Genentech accolade there are unsuccessful clinical trials and complications with marketed products. But the gains that counter such losses are impressive, and the increasing relevance of biotech since its inception in the mid-1970s has seen its appeal to investors, particularly large pharmaceutical firms, escalate rapidly over the past few years. Investors have been putting their energies into developing business models to withstand the volatility of the sector, hoping to reap the current and future returns that experts predict.

Collaboration is the lifeblood of scientific progress, and many significant steps within the biotech industry would not have been taken without it. It is logical then, that alliances among pharma companies, academic institutions and complementary biotech outfits are essential for both the biotech industry itself and those who seek to invest in it. Despite some fears that outright M&A could exacerbate volatility in the sector, activity has increased over the past few years, leading experts to predict that 2007 will see more of these transactions at higher premiums, driven chiefly by capital-rich 'big pharma' companies.

In the US today, more drugs are approved for marketing from biotech than from pharmaceutical sources. This trend was unheard of a decade ago, and provides an insight into the increasing dependency of pharma on biotech. Tightening product pipelines have put even the largest pharma companies under pressure to deliver something marketable, and perhaps the fastest way to achieve that goal is to acquire a selection, or 'portfolio', of biotech firms via M&A or informal collaboration. This strategy reflects sound logic – the more endeavours undertaken, the more chance there is that one of them will generate a blockbuster product. Improved chances of higher returns always attract capital from willing investors.

Formerly, pharmaceutical firms demonstrated but a passing interest, if any, in biotech firms still within the research and development (R&D) stage of the product life cycle, preferring to acquire within the later stages of Phase II, if not during Phase III. Investing time and resources any earlier was generally considered a fool's game, as development within the sector was, and still is, notoriously unpredictable. But this tactic has been re-evaluated in recent years – partially owing to a tightening in regulations that renders even relatively complete therapies a high-risk investment, but more importantly to the changing relationship between biotech and pharma. "As the number of later-stage opportunities shrinks, we expect to see more early-stage deals for promising new leads," predicts BioIndustry Association (BIA) Chair Dr Simon Best. "Capital is scarce, although there are some new sources available at later stages, such as royalty-based funding, revenue interest deals and special purpose vehicles."

Acquiring biotech firms without a readily marketable product can be an effective way for pharma to outsource the earlier stages of their own product development. This approach allows pharma to access innovations at the earliest stages of R&D, while freeing up enough of their own R&D budget to alleviate and diversify the risks involved. It also provides a solution, or at least a potential solution, to the threat created by expiration of patents on prize drugs. This development is also highly beneficial to biotech, which prior to this trend for earlier investment found it difficult to acquire funding for start-up R&D.

This change is precipitating something of a shift in the balance of power between the two sectors. Pharmaceutical companies increasingly concentrate on marketing finished products, preferring to delegate much of the actual science to their biotech divisions, who tend to be in possession of superior facilities, ideas, techniques and highly-skilled staff. In addition, as John Will Ongman, a partner at Axinn, Veltrop & Harkrider LLP, points out, "Large pharma, despite various efforts at giving freedom to its scientists, can never have the entrepreneurial degrees of freedom that are available to biotech. Biotech companies will continue to have a comparative advantage in discovering new compounds and pharma will continue to have a comparative advantage in the resources needed to support the FDA application process required to bring a drug to market and the marketing efforts needed to ensure its commercial success once approved."

As such, pharma as a whole is making a more concerted effort to seek out favourable partnerships, and is willing to invest a great deal of capital in securing them and the associated IP. Several high-profile cases in the US involving giants from the pharma sector exemplify pharma's outreach. December 2006 saw leading pharmaceutical corporation Eli Lilly, currently ranked tenth in Pharmaceutical Executive's global Top 50, offer $34 a share in order to acquire its biotech partner ICOS, at a total of $2.28bn, in the hope of turning a relatively informal product collaboration into a full-fledged merger. Although ICOS shareholders ▸▸

Tightening product pipelines have put even the largest pharma companies under pressure to deliver something marketable, and perhaps the fastest way to achieve that goal is to acquire a selection, or 'portfolio', of biotech firms via M&A or informal collaboration.

voted to accept the offer on 25 January 2007, some observers believed the bid dramatically undervalued the company, citing $40 as a more appropriate figure. This demonstrates the nature of the changing relationship between biotech and pharma – the former is growing aware of its value.

Another agent in the spate of biotech M&A is patent expiration. On expiry, other companies are legally allowed to manufacture generics or 'biosimilars' of the formerly patent-protected product. After enjoying a lawful monopoly on a product for a number of years, a company can see its profits take a sudden decline as the market is flooded with cheaper generic alternatives. This situation is precipitating a recent flurry of pharma/biotech mergers, but acquirers are advised to investigate the IP to the fullest extent possible before completion. "Acquiring certain rights in a target company's intellectual property is often the primary motivation for an M&A transaction in this industry – therefore intellectual property due diligence is a critical feature of any transaction," states Seth Levy, Of Counsel at Davis Wright Tremaine LLP. "A careful review of the IP rights at issue is imperative. Any patent rights at issue should be analysed in detail, including any relevant licence agreements and the potential for third party infringement."

In a sign of the times, Pfizer, currently the world's largest pharma company, announced its acquisition of biotech outfit Embrex in November 2006. Not only will such deals soften the blow of Pfizer's pending patent expirations, they will also allow its marketing function to remain innovative and topical. Embrex are best known for their line of poultry vaccinations, and the global threat of avian flu will undoubtedly satisfy the need of this big pharma company to stay abreast of current medical issues.

The generic threat is heightened by the incentives afforded under the Hatch-Waxman Act of a brief exclusivity period for the first company to bring to market a generic equivalent to an innovative drug. Innovators may opt to settle Abbreviated New Drug Application (ANDA) litigation with generic firms, under provisions that delay the generic's entry into the market. Since the beginning of 2004, brand-name drug manufacturers and generic drug applicants have been required to file settlements of ANDA litigation with both the Federal Trade Commission and the Antitrust Division of the Department of Justice within 10 days of the execution of these agreements. The Antitrust Agencies are especially concerned with 'exclusion payments' to delay entry of a generic. Despite some court decisions that took a more lenient view of exclusion payments, the regulators have reaffirmed their focus on and willingness to challenge settlements such as these.

It is certain that mergers, acquisitions and informal partnerships between biotech and pharma form a winning combination, and it is likely that this trend will continue for some time yet. Strategic collaborations can work if the companies are of similar sizes and exist comfortably in their own right, but any imbalance or dependency will generally lead to a formal merger. ■

Raising capital: venture capital, private equity and IPOs

2006 was a good year for venture capital investment in the life sciences (biotech and medical devices) sector. According to the NVCA (in association with PricewaterhouseCoopers) $7.2bn was invested in 731 deals, relative to 2005's $6bn across 647 deals. In addition, life sciences accounted for 28 percent of all venture capital invested, and was the most invested-in sector of 2006. Biotech also clinched the largest VC investment in the US when Kalypsys Inc. reaped $100m in its third round of VC investment, with 89 percent put up by previous investors Tavistock Life Sciences.

VC firms generally count fledgling companies to be among their main targets, but when investing in the biotech sector they seem to be eschewing early-stage deals in favour of more established entities. Stephen Oxley, European Chair of Pharmaceuticals at KPMG concurs. "VCs are seeking stronger proof-of-concept data than has historically been the case, which places an onus on biotech to have made greater progress pre-VC funding than was the case some years ago," he says. "As such, VCs are increasingly diverting biotech firms that have failed to reach this hurdle to other capital sources, such as regional funding and angel investors in order to attract investment."

Dr Best also acknowledges that the goal posts have shifted. "Venture capitalists are putting very little into early-stage companies, leading some companies to float at an early stage on the AIM as an alternative. Venture capitalists prefer companies that have a broad range of technology and strong management that can manage the well known and demanding challenges of the industry," he says.

But in the eyes of a venture capitalist, innovative technology will only take biotech so far. "Investors are increasingly wary of ventures that are pitched as being technology-driven, with a greater focus on companies that have a very clear and deliverable route from technology to product, with a definite emphasis on the latter," warns Mr Oxley. "Recent acquisitions have been exemplified by the target having a number of products in clinical development and also a defensible 'discovery engine' capable of producing more products of that class." It is clear, then, that investors have come to value the staff and IP rights as highly as the fundamental technology itself.

IPO and trade sales remain the main methods by which VC backers perform their exits, although the rise in formal M&A between biotech and pharma may see more VC outfits choosing that route in preference to IPOs. While IPO remains popular, the market at large is showing little evidence of progress, particularly in the US. "The IPO volume in the US markets during 2006 was $43bn, a 26 percent increase from $34bn in 2005, but pulling even with the $43bn volume that was reached for 2004," reveals Dr Joseph P. McMenamin, a partner at McGuireWoods LLP. "The 2006 volume, however, was less than half the volume that the IPO market achieved in each of 1999 and 2000. Therefore, the IPO market in the US is healthy, but not necessarily robust." Biotech has contributed ▸▸

significantly to recent IPO figures. Omrix Biopharmaceuticals held its IPO in April 2006 at $10 a share, for example, and on 22 January 2007 stood at $34.18 a share, for example. But that is not to assume that all biotech outfits have fared so well, and experts recommend that unless a biotech firm is prepared to brace itself against a drop in share prices, it may prefer to wait for better conditions.

To improve the likelihood of a successful IPO, Dr McMenamin recommends that companies adhere to the following criteria: current profitability; an FDA-cleared product facing little risk of any change in clearance status; a management team knowledgeable in product distribution and reimbursement; and a business plan that envisions an array of products for development in the near-term. Will Gould, Segment Head of Life Science Finance at Merrill Lynch Capital Healthcare Finance agrees. "Investors remain wary of single-product stories where the risk is binary, but strong management teams with a platform for developing new products fare better," he says.

Young biotech companies who have been declined for VC investment are increasingly opting for flotation on London's AIM in order to raise essential capital. The low regulatory burden is attractive to firms with little capital to spare at the time of flotation. The trouble is, life in the public limelight can be fraught with risk and long-term success is sporadic at best. Further, Mr Gould believes that IPO as a source of capital is currently unfashionable. "Companies have become more creative about accessing capital markets and finding alternatives, he says. "The emergence of growth equity funds, the availability of venture debt and royalty stream financing all give private companies access to capital and allow them to be more selective about whether and when to go public."

As for private equity investors, biotech has always been something of a challenge, and this is set to remain the status quo for the time being. Mr Gould asserts that the attentions of private equity firms are levelled elsewhere. "Leveraged buyout firms, which are accustomed to making controlling investments, have been particularly active in the specialty pharmaceutical market, where the focus is on sales and marketing , but have avoided research and early-stage development opportunities," he says. Such firms are more suited to deals within the pharma industry than their venture capital counterparts. "VCs cannot get the same leverage on their portfolio companies, so are more likely to spread their investments around by taking minority positions," says Mr Gould. The interest of private equity in pharma shows no sign of abating, and while the impending mass of expiring patents may yet have an effect, it is likely to be indiscernible for 2007 at least. ■

Intellectual property: the lifeblood of the drug development industry

In an industry as reliant on innovation and intangibles as biotech, a company's intellectual property (IP) is its most valuable quality, and ultimately critical to its overall value and attractiveness to investors. As such, a dependable IP development strategy is required in order to protect from competitors. This can be complex in that useful IP is not a stagnant quantity, and much of its importance lies in its potential for enhancement over what can be a rather long gestation period. Therefore, a thorough IP plan must be flexible and detail exactly how to make use of the associated rights, and account for any relevant legislation. Private equity firms and venture capitalists tend to value IP over a strong management team, and exercise lengthy due diligence accordingly. Companies seeking investment should therefore ensure that their future products will not infringe on any third-party patents, as few firms would risk the ensuing legal costs in the event of an infringement.

Patented IP is a significant asset for biotechs. Investors soon lose interest if IP exclusivity cannot be guaranteed. In the absence of a completed product, patents bring tangibility to an idea, creating a commercial tool whereby the holding company can attract favourable alliances and fend off rivals. But assembling patent protection is a complex and expensive process, particularly in light of the sector's collaborative tendencies, which span from early research and development (R&D) through to manufacture and eventual product sales.

Alliances with pharmaceuticals and the academic sector will be central to the ongoing growth of the biotech industry. But this can make it difficult to ascertain which party, in a legal sense, can be labelled as the true inventor. "Not all parties working on a project are inventors," asserts John Iwanicki, a partner at Banner & Witcoff. "Before the collaboration takes place, the parties should have a joint development agreement firmly in hand that clearly defines the role of each party in the process and obligates each inventor to assign their rights in the invention to a single entity. However, if joint ownership is the goal, then the obligations of each joint owner should be explicit." Without such an agreement, a worst-case scenario could see reagent suppliers and generic testing services assume equal credit for the innovation, and make use of it without paying royalties to the true inventors.

Parties should expect that disagreements will surface and act early to lay the groundwork for consensus building. "Open communication is extremely important," suggests Mr Oxley, "with each party identifying individuals who will be responsible for supporting the swift resolution of issues as they may arise. These safeguards should ensure the ability of each party to exercise appropriate financial and operations control to protect their IP." To the same end, it is wise to establish material transfer agreements that lay claim to any invention resulting from external testing of materials provided by the true inventor, which should alleviate the potential for costly and time-consuming litigation in the future.

The matter increases in complexity when collaboration is spread across various countries as well as sectors. While there are arguably some areas wherein patent laws are largely standardised, it can be unwise to make ▸▸

a decision based on that assumption. By treating each country and situation as distinct and separate, the companies involved can be prepared to amend their IP protection accordingly so as to ensure that they will be granted patent protection. "Strong patents protecting a core technology are critical, and can increase in attractiveness if the patent protection obtained by the company accurately overlaps with the international market for the technology," says Mr Levy. "Companies tend to focus their patent procurement efforts on the jurisdiction in which they are located, yet disregarding major markets can substantially undercut the ultimate value of the intellectual property," he adds.

One of the more pressing concerns in cross-border collaborations is not necessarily the patent laws themselves, rather the manner in which they are enforced. Companies that have taken part in cross-border alliances should act with caution, warns Mr Iwanicki. "While the patent applicant may expect that the granted patent right will be respected by competitors, and on suspected infringement, that the patent rights will be strictly enforced by foreign courts, these expectations may not be realistic. Litigating in a foreign land against a home town company can be a difficult, expensive and uncertain task." Local governments are unlikely to enforce a regulation at the expense of a domestic firm, and the holding company can spend a lot of time and money on what can ultimately be a fruitless endeavour.

In some cases, it may be that the price for market exclusivity is just too high, in which case it is prudent to seek alternative means. One of the more profitable methods of avoiding such litigation is licensing any foreign competitors under patent rights in exchange for royalties. Of course, retaining exclusivity is still the ideal objective, particularly in the eyes of investors keen to keep return potential as high as possible. Companies remain aware of the threat from generic products in overseas regions and develop a strong patent enforcement strategy to counteract it.

As the biotech sector reaches a stage where a great number of patents are fast approaching their expiration date, a number of legislative issues within IP law have been highlighted. Each of the major global markets has different issues to contend with, although perhaps the most polarising scenario exists in the US. Having proposed changes at the start of 2006, the US Patent and Trademark Office (USPTO) is in the process of reducing the number of 'continuing' patent applications an applicant is allowed to file. After considering relevant criticism, the USPTO perceived that current legislation surrounding this particular type of patent was unfair to the public. The ability of a claimant to file as many claims as it wishes to cover the development of a product seemed to precipitate confusion as to what is, or could potentially be, covered by a patent application.

The changes propose that only one continuation be allowed. When filing the 'parent' patent, an applicant should proceed to outline all possible products and innovations that could occur as a result of the applicant's work. A continuation will only be passed only if an applicant can provide strong evidence why the new development could not have been covered in the original patent. This has proven to be somewhat unpopular among patent agents, attorneys and general executives, as verified by the president and chief executive of the Biotechnology Industry Organisation (BIO), James Greenwood: "We generally support proposals that seek to harmonise US patent law with those of other countries, but some of these proposals, marking the most dramatic changes to patent examination in decades, contain provisions which would make it easier to challenge patents and may therefore create a disincentive for innovators and potential biotech investors. Retaining strong patent protection is critical to encouraging innovation and promoting the investment necessary to develop innovative therapies and technologies," he says. But no-one is certain of the effect the alterations will have on the acquisition of and costs surrounding biotech patents.

It does ring true that current trends in US patenting laws suggest that seeking patent protection for biotech innovations is increasingly difficult.

It does ring true that current trends in US patenting laws suggest that seeking patent protection for biotech innovations is increasingly difficult. The US Supreme Court is latterly reviewing the 'obviousness' standard (also known as 'inventive step') that an invention must satisfy before qualifying, whereas the lower courts are focusing on reviewing existing patents in light of the new standard. These changes have been prompted by developments in the case of KSR v. Teleflex (2006), where the plaintiff, Teleflex is suing KSR for alleged infringement on an automotive innovation. Developments since the case opened indicate that the 'teaching-suggestion-motivation' (TSM) method, used to determine 'non-obviousness' is now as much on trial as KSR. Mr Levy expresses his concern: "A change to this standard could call into question the validity of many existing US patents and raise the bar for obtaining patent protection in the first place." His view is shared by many industry observers, who anticipate additional and rather unwelcome complexity in what is already a regulatory minefield.

Much of the perceived virtue of TSM lies in applying its criteria at the time of invention, thereby eliminating biased obviousness that comes with hindsight. KSR, however, have argued that much of development can be considered as combinations or amendments of pre-existing inventions, and that TSM favours synergistic creation. The court has given weight to this observation, and it is expected that 2007 will see the lower courts use methods other than TSM in order to establish non-obviousness, although TSM is unlikely to cease altogether. In cases where TSM is set aside, however, these developments are likely to make acquiring a patent more difficult.

Nor is KSR the only case with potential to cause significant changes in law. MedImmune, issued January 9th, reversed the Federal Circuit on the proper legal standard for a justiciable controversy in declaratory judgment cases. Generic drug manufacturers will now be able to test the validity waters against pioneer patent-protected drugs long before they go to market. Experts believe MedImmune may open the floodgates for patent validity challenges by licensees who will no longer have to breach their patent licenses to have standing to sue. Patent holders who send out notice and warning letters to potential infringers before filing suit are now at risk of being hailed into a forum chosen by the accused infringer.

Establishing and enforcing a patent under European law does not involve these specific issues, but raises others of equal relevance to the biotech sector. Patents sought within Europe are not enforced by the EU, or even a central court, but are granted and enforced by the individual member states – although the EU has issued specific directives to deal with problematic side-effects of this structure, such as 'forum-shopping'. While the notion of a single unitary patent system within Europe has been around since the 1970s, a formula to achieve this has not been agreed to date. Within biotech, however, the EU has seen it fit to intervene, and in a directive finalised in 1998 it became EU law that living things, or processes that result in the creation of living things are not patentable, as their exploitation is contrary to public morality. As the biotech industry increasingly veers into genetics, this directive makes it very difficult for companies to protect their IP from rivals. Many are resorting to trade secrets, which are difficult to maintain in a collaborative situation and whose protection is not enforceable by law. In a market that ultimately seeks to expand through mutually beneficial research, trade secrets can be counterproductive and may stifle innovation.

Patent reform is sought the world over, but has proved exceedingly difficult to enact – particularly as patents are used differently within various industry sectors. Mr Ongman highlights the main conflict. "Biotech and pharma companies rely on patents to surround and support a product which has taken years and many millions of dollars to develop, whereas IT moves faster and is built on many pieces of intellectual property." Such diverse interests require patents to satisfy almost competing criteria. Mr Ongman continues, "The biotech/pharma sector generally wants its IP to be difficult to overturn while IT generally wants to prevent IP on a miniscule portion of the product to bar the entire product." Resolving the issue of patent reform will have to take into account these contrasting purposes. Considering the outright contradiction between certain requirements, a universal resolution may not be reached at any point in the near future.

Trademarks comprise an important part of an overall IP strategy, allowing a company to associate itself with a brand or a collection of elements in the minds of the consumer market. Mr Iwanicki proposes that "Consumers may be more likely to purchase a branded product that has been widely available based on the perception of better quality, even though the product may be more expensive when compared to a non-branded product. Therefore, when combined with strong patent protection, trademarks can provide desirable market exclusivity."

Biotech firms should take note of reliable trademarks such as these, which can provide a competitive advantage when products hit the shelves. Successful brand names generally distinguish their psychological aspects from the reality of the product. An infant suspension product named 'Baby Medicine', for example, is unlikely to be distinguishable from other suspensions, whereas 'Calpol', as a neologism, is associated with the attached product only. Trademarks are not limited to branding, and include an array of attributes such as words, logos, slogans, shapes and even colours or sounds. Eli Lilly made the circular half-green, half-cream design of Prozac a trademark, and have enjoyed a virtual monopoly on anti-depressants ever since its introduction in 1988. ■

Legal & regulatory challenges

Few sectors are subject to as many regulations as the pharmaceutical industry, and its increasingly close relationship with biotech is causing their fates to intertwine. Dr Karen Gilberg, a senior vice president and head of the Healthcare Practice at Davies Consulting Inc., asserts that "Small biotech companies have often believed that, due to the nature of their products and the diseases which they treat, they will be subject to less stringent oversight by regulatory agencies and will have no competition from generic products." But, she adds, biotech has discovered the falsity of this statement the hard way, as pharma did previously, and as such are putting a lot more time into assembling a solid business plan that accounts for any potential regulatory impediments and will see a product through its long gestation period to commercialisation.

Even in the event that a product should prove to be marketable, Mr Ongman recommends caution, particularly in the US. "Executives should be wary of limits on the firm's ability to price the drugs at a level that makes commercialisation worthwhile," he says. "The emergence of a Democratic Congress may precipitate direct or indirect curbs on the ability to charge commercially appropriate prices." A product can be commercially unviable even if it is scientifically sound, so biotechs ▸▸

should be aware of the risks and aim to avoid unnecessary costs throughout development. Naturally, there are unavoidable costs in adhering to ever-tightening regulations regardless of the strength of a business plan, particularly in light of those which seem to be calling for increasingly unreasonable levels of perfection. Indeed, the costs for developing a biotech product are, on average, $800m.

Experts are concerned that if regulatory stringency continues, the supply of marketable products will dry up. As it is, pipelines the world over are steady at best, although many perceive a decline. This could well precipitate a dramatic change in the sector's economic model, although concerns remain largely speculative. Certainly, many sector insiders take a different view on the role of regulation within the biotech and pharma industry. "A strong regulatory environment is critical for success," argues Mr Greenwood. "The recommended improvements to the Prescription Drug User Fee Act (PDUFA) recently announced by the Food and Drug Administration (FDA) will allow continued enhancement of FDA's post-market safety capacity and help ensure careful, timely and transparent review of new drugs and biologics." However, Mr Greenwood emphasises his concern over the notion of "measures that limit patient access to innovative therapeutics and discourage innovation".

Recent high-profile failures in the late stages of biotech production have brought safety issues and product liability to the forefront of regulation as a whole. This has not yet had a massive effect on existing regulations, but it is certainly the case that their application is somewhat more stringent. Late stage mistakes often involve human subjects, which never fails to grab the unwanted attention of the international media, particularly when big pharma are also involved. December 2006 saw an example when the world's largest pharmaceutical company, Pfizer, was forced to withdraw torcetrapib, a drug developed to treat hypercholesterolemia, when test subjects demonstrated an unusually high mortality rate. This was of particular note to the media as Pfizer had been expressing confidence in the product up until 30 November 2006 – about three days before the product was withdrawn.

In the US, federal product liability trials involving pharmaceutical products outnumber those in any other sector, representing approximately one-third of all such cases. "The image of pharmaceutical houses has suffered in recent years, creating the perception, if not the reality, that these companies may be more vulnerable to juror animus than was the case was years ago," Dr McMenamin says, adding that "many jurors and even some courts have lost sight of the fact that all therapies carry inherent risks." Such attitudes and general media representation can lead to a negative multiplier or 'me too' effect, wherein multiple cases of the same ilk, or in the same sector, arise in the wake of a high-profile verdict and effectively become so stigmatised that jurors entertain an unkindly disposition and unknowingly continue to precipitate the effect.

In addition, big pharma is generally synonymous with pools of disposable capital, generating interest from those plaintiffs who anticipate a sizeable out-of-court settlement. In the event that the case is upheld, representation is becoming ever-easier in the wake of the 'no win – no fee' trend, rendering the cost and very idea of litigation far less intimidating. Each case should be judged on its own merits, although there are ways companies can limit the impact of a failed product. "Many, if not all serious adverse effects could have been predicted from preclinical and early clinical data," Dr Gilberg believes. "As a result, it is critical that pharma and biotech companies find ways to objectively assess the preclinical and clinical data supporting their products and actively investigate findings which may point to serious adverse effects and define the characteristics of patients who are at most risk." At present, it seems unlikely that costly legal issues will precipitate a widespread product shortage, although economic sense dictates that costs will continue to rise.

The menace of product liability in the US does not begin and end with personal injury claims, but has seen an alarming increase in the level of marketing fraud claims based on state consumer protection statutes. These are increasingly presented as 'class actions', where a large group of people aggregate similar grievances and take joint representation in a single case, which makes court procedures more efficient and alleviates congestion. Quite aside from the inevitable increase in damages that may be awarded, the relevant procedural and substantive law of individual states can differ quite dramatically, and the tendency is to 'shop' for the most consumer friendly state law. Tort reform in such jurisdictions may be rudimentary or non-existent. In these cases, the fight over class certification may be critical.

Looking ahead, the concerns of many biotech firms lie in their attempts to prolong their longevity within a consistently volatile industry. There is some truth in assuming that a formulaic approach to competitive success fails to anticipate all possible pitfalls. But Dr Gilberg believes that "The companies that have consistently had the most positive reputation with regulators, investors, physicians and patients have been those with the following attributes: products in therapeutic areas with medical need; transparent and honest interpretation of data; and an open and proactive response to negative data with clear messages to customers on what to do as a result of these findings." It is clear that companies that adhere to such guidelines, regardless of any short-term pejorative effect, will retain the trust of those in whose hands lies their survival. ■

CONTRIBUTORS

John Will Ongman is a partner at Axinn, Veltrop & Harkrider LLP. He can be contacted on +1 (202) 721 5400 or by email: jwo@avhlaw.com

John Iwanicki is a partner at Banner & Witcoff. He can be contacted on +1 (617) 720 9600 or by email: jiwanicki@bannerwitcoff.com

Dr Simon Best is chairman of the BioIndustry Association (BIA). He can be contacted on +44 (0)20 7565 7190 or by email: admin@bioindustry.org

James Greenwood is president and chief executive of Biotechnology Industry Organisation (BIO). He can be contacted on +1 (202) 962 9200 or by email: jgreenwood@bio.org

Dr Karen Gilberg is a senior vice president in the Healthcare Practice at Davies Consulting Incorporated. She can be contacted on +1 (301) 652 4535 or by email: KGilberg@Daviescon.com

Seth D. Levy is Of Counsel at Davis Wright Tremaine LLP. He can be contacted on +1 (213) 633 6800 or by email: sethlevy@dwt.com

Stephen Oxley is European Chair of Pharmaceuticals at KPMG. He can be contacted on +44 (0)20 73114763 or by email: stephen.oxley@kpmg.co.uk

Joseph P. McMenamin is a partner at McGuireWoods LLP. He can be contacted on +1 (804) 775 1015 or by email: jmcmenamin@mcguirewoods.com

Will Gould is director of the Healthcare Finance Group at Merrill Lynch Capital. He can be contacted on +1 (212) 449 1000 or by email: william_gould@ml.com

AIRTIGHT PROTECTION.

GREAT FOR PASTA, SOUP AND PATENTS.

Nothing escapes our attention. At Banner & Witcoff, years of experience have taught us where to look for opportunities and risks to your patents, copyrights and trademarks. Fortune 500 companies and multinational corporations trust us to keep their IP rights unassailable. Should someone infringe, we move decisively to protect your rights, with a team of top litigators schooled in the intricacies of IP law.

BANNER & WITCOFF, LTD.
INTELLECTUAL PROPERTY LAW

WWW.BANNERWITCOFF.COM | CHICAGO | WASHINGTON | BOSTON | PORTLAND