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Special
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InFocus

Life sciences & healthcare legal e.bulletin



Introduction

This special edition of InFocus is published to coincide with Taylor Wessing's sponsorship of [Life Science Alliances World 2007](#). The conference, organised by Terrapinn, is being held at the Victoria Park Plaza Hotel in London on 16-18 April 2007.

Key issues discussed in this special edition include:

- The OFT report on the Pharmaceutical Pricing Regulatory Scheme
- "Best endeavours" and "reasonable endeavours". What do they mean?
- The private M&A process in the UK
- The ABPI code of practice one year on
- IP valuation in pharmaceuticals and biotech by guest writer, Jo Pisani, of PricewaterhouseCoopers LLP

In this special edition we also include details of some of our [recent life science deals](#).

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The new UK Code of Practice for the Pharmaceutical Industry 2006 (the “2006 Code”) came into force on 1 January 2005. This article examines recent cases under the 2006 Code that relate to two of those changes, and looks at the guidance in those cases from the body which operates the 2006 Code, the Prescription Medicines Code of Practice Authority (the “PMCPA”)

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Jo Pisani, our guest writer, is a Director in the Pharmaceuticals and Healthcare team at PricewaterhouseCoopers LLP. In her article she outlines a method for producing a robust model for valuation of Intellectual Property that is employed by leading edge pharmaceutical companies

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Pharmaceutical pricing: time for a debate – and a Royal Commission?

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The OFT's report into pharmaceutical pricing raises profound issues. The outcome will decide whether the UK will continue to be a centre of excellence and innovation for the pharmaceutical sector. The Department of Health, with a clear interest in reducing the nation's drugs bill, is not in a good position to lead this debate. An independent and authoritative body is needed to undertake a detailed investigation and make recommendations. A Royal Commission would fit the bill.

The Office of Fair Trading (OFT) has decided that there is a compelling case for reform of the way in which drugs are reimbursed in the UK. The Financial Times concluded that the OFT report was "Sensible in its aims. Somewhat undercooked and perhaps a little naïve in some of its conclusions".

The Pharmaceutical Pricing Regulatory Scheme (PPRS) provides a cap and floor mechanism for regulating the price which the NHS pays for drugs. In recent years this has only been used to impose one-off industry-wide price reductions: a blunt instrument. There is also a complex profit control mechanism which the OFT concluded didn't achieve its objective.

The OFT, in the first systematic review of the PPRS in 50 years, can hardly be accused of being timid in its proposals for reform. It proposes a value-based pricing system coupled with both a before launch and an after launch review mechanism. Value-based assessments will be made by the National Institute for Clinical Excellence (NICE) and its counterparts in Scotland and Wales. Pricing negotiations will be undertaken by the Department of Health based on the value for money assessment as well as such matters as rebates and brand premiums. If agreement is not reached reimbursement will be refused. The possibility is floated of eventually creating a fully-fledged Medicines Pricing Commission.

Different stakeholders will, undoubtedly, take different messages from the report. Research-based companies, generics, bio-similars and parallel traders will all have a different view on what is best for them. The Department of Health has 120 days to consider the report, a period that grossly under estimates the complexity and importance of the issues involved. Since this period is likely to be accompanied by frantic lobbying by many in the pharmaceutical industry it may be helpful to consider why the OFT reached the conclusions that it did, whether other options for reform merit consideration and, if so, what further consideration is required.

The OFT's key finding is that the profit control mechanism within the PPRS does not achieve its objective. It doesn't act as a constraint for most companies and might even adversely affect some small, UK-based, companies with high R&D investments. Perhaps more importantly the OFT was clearly seriously concerned about the potential for dulling incentives by a profit control mechanism that doesn't take any account of the relative value of drugs. Furthermore, the OFT concludes that there is little evidence that general practitioners are aware of the pricing cost to the NHS of their prescribing habits. Indeed the OFT's survey concludes that GPs' price awareness of the drugs they prescribed is, statistically, no better than guesswork. If a value-based system is to be introduced, then improved mechanisms are going to have to be found to inform GPs and a relatively centralised system will be required to implement it.

There is one finding that can be expected to ensure that the report is at least partly acted on. This is the conclusion that for five of the largest selling drugs in the UK savings of £510 million per annum could be achieved if therapeutically equivalent and closely substitutable generics are supplied. Of course, there will be vigorous debate over whether a particular drug is or is not therapeutically substitutable but one suspects that this will cut little ice with the Treasury and the Department of Health. Perceived efficiency savings of this magnitude are likely to be just too large to be ignored.

To suggest that the report is simply an attack on big-pharma is mistaken, as can be seen from the OFT's forceful rejection of calls to curb the marketing activities of pharma companies in the UK which the OFT estimated at £850 million per annum as well as its support for continued investment in the UK.

Rather disingenuously the OFT concluded that the PPRS, in either its current or in a future form, should be regarded as a means of exercising buyer power and not as a regulatory measure. If this is really the objective then it is perhaps surprising that the OFT didn't propose demand-side measures to encourage more centralised procurement.

Since a central theme of the report is that there should be a value-based regime it is disappointing that the report avoids stating what the OFT means by this term. A common theme is that price should be linked to benefits to patients although the OFT says that it is sympathetic to this concept being expanded to include carers. There is no serious attempt to address the difficult issue of drugs that are particularly beneficial for small patient sub-groups but cannot be shown to benefit a wider patient group. Perhaps most surprisingly there is no indication of how benefits to the NHS are to be quantified. It seems to be assumed that they are to be equated to benefits to the patient. Yet a drug that avoids or reduces hospital admissions clearly has a value to the NHS as well as patients although their values are likely to be different. While raising the difficulty of quantifying value-based incremental improvements the report offers no indication as to how this important subject is to be addressed.

While strongly advocating generic prescribing the report nevertheless acknowledges that when a drug comes off patent, GPs may prefer to prescribe a brand that patients are familiar with. To this end it recommends that originator brands should be reimbursed at up to 25% above the generic price. There is also the interesting proposal that companies might be able to retain their higher prices in return for making a payment to the NHS. Mechanisms such as these may lead to pharma companies paying for generics to stay off the market as has been the case in the USA even though this is likely to infringe the competition rules.

The OFT's support for generic companies contrasts with its approach to parallel traders. The OFT seems to want to keep the threat of parallel trade as a mechanism to encourage research-based pharma companies to agree a higher price cut than would otherwise be the case. The OFT envisages a win-win situation with benefits accruing from parallel trade being retained by the NHS rather than being lost to parallel traders. One has to question how realistic this approach is. Apart from any other considerations diverting savings from the pockets of parallel traders to the NHS doesn't mean that the loss to R&D and innovation will not be just as real.

Heavyweight lobbying and legal challenges, however much discouraged by the courts, seem set to become established features of getting new drugs approved. With an average cost of each new approved drug of \$800 million the sums involved are simply too large for pharma companies to be willing to accept a ruling from NICE that a drug is not providing sufficient value added benefits to be reimbursed at all or to be reimbursed profitably. This tension will be even greater if a drug is demoted after a five-year review. The proposal that risk sharing agreements could be negotiated where there is genuine doubt over the efficacy of a drug seems unlikely to answer the difficulties associated with a scheme that requires an assessment before reimbursement can be obtained.

Few in the industry share the OFT's confidence that a fast track approval of new drugs can be accomplished within a few weeks of marketing authorisation being granted. The suggestion that five yearly reviews for all drugs will only cost the government an additional £6.5 million per annum seems wildly optimistic. Add to that the sclerotic effect of quinquennial reviews in industries such as water and airports and one starts to appreciate the scale of the likely consequences if the OFT's proposals are implemented. The risk that innovative medicines will be assessed against low-cost quasi-comparators is very real.

The report's emphasis on increasing buyer power with the threat that unless agreement is reached on price then reimbursement will be refused, undermines the attractions of a value-based approach. Whatever institutional framework is put in place will have to be demonstrably independent of the NHS and Government if it is not to be regarded as simply a means of reducing NHS spending on drugs and choice. In this respect the proposal that the Department of Health should undertake the price negotiations fails miserably.

There is also the very real concern that the UK's reputation as a centre of excellence for research and innovation for the pharmaceutical industry will be put at risk. The report analyses in some detail the factors that lead to pharma companies locating their activities in the UK. At present new drugs tend to become available to patients in the UK earlier than in many other EU countries. This is partly due to the fact that at present there is no pre-launch delay while reimbursement approval is obtained. It is counterintuitive to expect pharma companies to continue to treat the UK as a favoured market when they are faced with a new regime that seems likely to deliver delay, lower profits, risk-sharing, five yearly reviews and uncertainty. One needs to look no further than some of our neighbours in Europe to appreciate that pharma companies will tend to launch new drugs in the markets that seem likely to provide the greatest commercial return most quickly.

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It is arguable that the OFT has placed too much emphasis on price as a measure of competition. The pharmaceutical industry is characterised by fierce competition in terms of innovation that leads to a continuous flow of new drugs. Investment in R&D has to be funded out of a sufficient, sustainable and secure level of profit. The OFT's report is remarkably thin on the interrelationship between profitability and investment.

The OFT has started a debate but the issues are far more complex than the some of the "solutions" proposed by the OFT suggest.

Questions that will need to be addressed in the forthcoming debate include:

- Ensuring genuine value-based decisions and not merely the lowest cost option so as to reduce NHS spending on drugs;
- Guaranteeing that the bodies undertaking the assessments do so to a world-class standard and are genuinely independent of political and spending pressures;
- Increasing resources to ensure prescribing doctors are better informed of the value of the drugs that they prescribe;
- If NICE and its counterparts in Scotland and Wales are considered to be best equipped institutions to undertake the complex assessments required is it efficient to have three such organisations with different remits and agendas even if there are mechanisms to prevent duplication?
- At what level should pricing negotiations take place? Centrally, locally or a combination of the two with local NHS Trusts and organisations negotiating additional discounts and rebates to reflect local use and demand?
- What is the correct balance between innovation and the short-term expediency of lower price? Is it really realistic to think that an originator pharma company can achieve an adequate return on investment in only five years even assuming the drug is sufficiently value enhancing to qualify for reimbursement in the first place;
- How does any new pricing mechanism square with the patent regime? Will it encourage more patent litigation to ensure that competing products are kept off the market at the time of five-year reviews? Will a Supplementary Protection Certificate be worth having?
- If there is to be a pricing review should it be deferred until after the expiry of relevant patents or, if later, the grant of a generic marketing authorisation?
- How should the UK balance the need for value for money with the need for a wide range of effective pharmaceuticals?
- Is it appropriate for millions of pounds invested in R&D and clinical trials to be negated simply on the grounds of value for money? Regulators, since this is what they will be whatever label is applied, have a poor record of picking winners;
- If, as the OFT suggests, the pharmaceutical sector is a dynamic, innovative, industry with new products leapfrogging older products this suggests a highly competitive supply side. If that is the case, and the difficulties are on the demand side, then it is perverse artificially to strengthen the demand side. If the ability of buyers to exercise the market power that they ought to have is weak then the logical step is to correct demand-side weaknesses and not risk artificially weakening an innovative sector.

The OFT had a choice. It could have referred the matter to the Competition Commission if it had reasonable grounds for suspecting that a feature of the market had an adverse effect on competition. Instead, it chose to undertake an investigation using its own general powers to prepare reports. Where a feature of a market has an adverse effect on competition the OFT's role is primarily to act as a first filter leaving the Competition Commission to undertake an in-depth investigation and to find solutions. Instead, the OFT has produced a report with a number of far-reaching proposals, some of which are arguably outside its remit and its experience, and left it for the Government to make a decision.

So how should the deficiencies in the present system be corrected in a way that leads to patient benefit, the retention of the UK as a centre of excellence for pharmaceutical innovation, a more value-based system and a light regulatory touch?

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Whatever decision the Government eventually takes it will have wide-ranging ramifications. Many will be concerned at the temptation to go for a quick fix and that the Government will follow the OFT's recommendations. This would be a big mistake. There are simply too many complex, and inter-related, issues that need to be resolved. Whatever the outcome, it is essential that it is demonstrably fair and practical. It must also be in the interests of the various strands of the pharmaceutical industry as well as patients and the public purse. The OFT has played an important role in kicking off the debate. What is now required is an independent enquiry to look at all the issues in depth and to make authoritative recommendations. A reference to the Competition Commission by the Minister of Health can only address any competition issues. It cannot deal with the wider policy and institutional issues that the OFT has identified. At the very least, serious consideration now needs to be given to establishing a Royal Commission.

Martin Baker

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The Private M&A Process – tips and strategies for a marriage made in heaven

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Whether buying or selling as part of a private M&A deal, there are a number of key stages to the process. These are relevant whether or not the target is a company (to be acquired by way of a share sale and purchase) or a business (an asset sale and purchase).

Initial steps

A vendor will usually require any prospective purchasers to sign a non-disclosure agreement (“NDA”) under which the prospective purchasers agree not to disclose any confidential information which the vendor provides in relation to the proposed sale. Even with an NDA in place, a vendor may wish to hold back key information until after it has received a bona fide indication of interest from prospective purchasers, such as an initial offer.

Due diligence

The due diligence process enables the purchaser to find out more about the target, and to assess more accurately what they are willing to pay to do the deal.

Purchaser's perspective

Access to a data room containing detailed information on the vendor and their business will enable the purchaser to:

- assess whether the proposed transaction is as attractive as they had first thought;
- determine, confirm or adjust their valuation;
- consider specific terms of the deal which will need to be agreed, such as assets to be acquired, or representations and warranties to be given;
- allocate the risk associated with specific issues between them and the vendor;
- examine more closely any key intellectual property owned or used by the vendor; and
- Identify any “deal breakers”, such as material issues surrounding ownership of key intellectual property.

Vendor's perspective

A vendor can ease the sale process considerably by preparing well in advance a data room of all relevant documents on the target, and assembling a deal team who will be available to answer questions from prospective purchasers. One point to remember is that if an online data room is being used, any information that is available will no longer be privileged. Preparing well in advance for due diligence can help to identify matters that should be rectified before due diligence begins. A frequent issue is securing the rights to intellectual property.

Term sheet

The parties will usually agree a term sheet (or “heads of terms”) setting out the framework of the deal before thrashing out the detail in a full sale and purchase agreement. The term sheet, which will generally not create a legally binding obligation on either party (other than in relation to confidentiality and exclusivity), will typically cover:

- the consideration, including any milestones if there is an earn out;
- liabilities under warranties;
- retention of key employees;
- non-compete covenants;
- escrow arrangements under which funds may be held in an escrow account pending satisfaction of a specified condition (or conditions) or in case there is a warranty claim;
- assignments and/ or licences of intellectual property; and
- any exclusivity period during which the vendor will not negotiate with any other party.

There is a strong temptation for vendors to sign term sheets as soon as the consideration has been agreed. Generally this is a mistake, as the more that can be agreed regarding the issues mentioned above, the smoother the negotiation of the share purchase agreement (SPA) is likely to be. Furthermore, if the target has institutional shareholders it must be established whether they are prepared to give warranties. If not, then the other shareholders must agree with the purchaser the amount of their liability.

Warranties

Once a term sheet has been signed the negotiations of the SPA will begin. One of the most contentious areas and therefore heavily negotiated aspects of any SPA is likely to be the warranties.

Warranties are contractual statements in the form of assurances to the purchaser as to the condition of the target. They redress the balance, to some extent, from the position at common law which is encapsulated in the Latin phrase “caveat emptor”: let the buyer beware. Without warranties or other contractual protections, there is no statutory or common law protection for the purchaser as to the nature or extent of the assets and liabilities he is acquiring.

Warranties are often used by prospective purchasers as a means of flushing out information about the target, and re-allocating risk as between vendor and purchaser. They also provide the purchaser with a right of redress if the target turns out not to be as the vendor had led him to believe.

Warranties v. Indemnities

Warranties cover every aspect of the target and should be based upon the results of a purchaser’s due diligence. The number and scope of the warranties relating to a particular aspect of the target depend on its importance. For example, there are likely to be extensive intellectual property warranties in an agreement relating to the purchase of an IP-rich target. If there is a breach of a warranty, the purchaser will be able to claim damages from the vendor provided the effect has been to reduce the value of the target.

An indemnity is a promise to reimburse the purchaser in respect of a particular liability on a pound for pound basis. It does not require the purchaser to mitigate his loss or to prove that there has been a reduction in the target’s value. Indemnities are most appropriate to cover known specific risks such as patent infringement, breach of contract or tax liabilities.

How do vendors limit their exposure under warranties?

A vendor will usually impose time limits during which a purchaser can claim under the warranties, as well as minimum and maximum claim amounts. A limit of two to three years is typical for non-tax warranties, with a longer period of seven years for tax warranties.

The principal means for a vendor to seek to limit his exposure to warranty claims is through disclosure of any facts that give rise to a breach of a warranty. If these facts are fairly disclosed to the purchaser before the sale and purchase

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agreement is signed, the purchaser will not be able to make a claim for the breach. Disclosures will be set out in a "Disclosure Letter", which will include general and specific disclosures. Examples of general disclosures are the contents of certain public databases such as Companies House or the Trade Mark Registry, which the purchaser can search. Specific disclosures are clear, unambiguous factual statements relating to specific warranties.

Simon Walker spoke on this topic at the "Life Sciences M&A and Strategic Alliances" Conference on 29th March 2007 at the Millennium Hotel, Knightsbridge, London.

Simon Walker and Tim Worden

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"Best endeavours" and "reasonable endeavours": What do they mean? [Back to contents](#)

Introduction

Requirements to use "best endeavours"¹ and "reasonable endeavours" appear in many contracts but what do they mean under English law? Contracts often contain expressions that are intended to define the efforts that should be made by one of the parties to achieve a particular outcome, but these terms are prone to being misunderstood.

A recent English case² has held that, as a matter of law, language and business common sense, the terms "best endeavours" and "reasonable endeavours" do not mean the same thing: legally, the former imposes a more stringent obligation than the latter. In light of that, and in the interests of commercial certainty, there is a current need to define the distinction between these two oft-used terms, the scope of the obligations imposed by them, and the commercial contexts in which they may usefully be employed.

In light of this most recent judicial authority, this article examines English case law with respect to endeavours obligations, and sets out some drafting recommendations in light of those cases.

Absolute obligations

Before analysing the standards imposed by "best endeavours" and "reasonable endeavours", we shall briefly consider absolute obligations.

The highest obligation in any contract is the absolute requirement to achieve a particular outcome. This will usually be indicated by words such as "shall", "procure" and "ensure" but many other words and expressions will have the same effect. For example, a contract might say that "*The Researcher shall complete the Research Project and deliver the Report to the Company by no later than the Project Completion Date*".

Not even these apparently absolute obligations are always absolute. For example, unless the agreement says otherwise in very clear terms, if one party prevents or obstructs the other from carrying out its obligations, no liability will arise as a result of that failure.

Such obligations are, however, relatively straightforward and the principles which attach to them are reasonably well understood. Confusion and uncertainty arises where parties attempt to impose some form of legal obligation on each other but intend that that obligation should not be absolute. This may be the case where the parties recognise that a particular task is difficult, subject to numerous variable factors, or otherwise uncertain.

Best endeavours

The highest form of qualified obligation that is generally in use is the requirement that one party should use its "best endeavours" to do a task or to achieve an outcome. For example; "*The Supplier shall use its best endeavours to provide the Service in accordance with the Service Level Agreement set out in schedule 1*".

¹ Alternatively, "best efforts". There is no distinction in law between the words "endeavours" and "efforts"

² Rhodia International Holdings Ltd and anor v Huntsman International LLC [2007] EWHC 292 – see below

In **Sheffield District Railway Co v Great Central Railway Co [1911] 27 TLR 451** the court stated:

"We think 'best endeavours' means what the words say; they do not mean second-best endeavours... They do not mean that the limits of reason must be overstepped with regard to the cost of the service, but short of these qualifications the words mean that the Great Central Company must, broadly speaking, leave no stone unturned to develop traffic on the Sheffield District Line."

Just over 70 years later, in **Pips (Leisure Productions) Limited v Walton [1982] P & CR 450**, the court held that:

"'Best endeavours' are something less than efforts which go beyond the bounds of reason but are considerably more than casual and intermittent activities. They must at least be the doing of all that reasonable persons could do in the circumstances."

On the other hand, in **Midland Land Reclamation Limited and Anor v Warren Energy Limited (1997) Unreported** the judge said: *"I reject the submission made on behalf of the Defendant that a "best endeavours" obligation is the next best thing to an absolute obligation or a guarantee"*.

The case of **Terrell v Mabie Todd & Co [1952] 69 RPC 234** was about a contract under which the defendant agreed to use its "best endeavours" to exploit inventions and designs licensed to it by the claimant. The claimant said that the defendant had failed in those obligations and sued for damages.

The judge disagreed with the defendant who argued that the obligation only required it to do *"that which was commercially practicable"* and said that the obligation went further, namely *"to do what they could reasonably do in the circumstances"*. In the circumstances what was reasonable was *"...what a reasonable and prudent board of directors acting properly in the interests of their company and applying their minds to their contractual obligations would have done"*.

It is clear that an English court's interpretation of the term "best endeavours" is dictated entirely by the facts of the particular case.

The case of **Rackham v Peek Foods Limited [1990] BCLC 895** appears to suggest that a "best endeavours" obligation can be worth very little. In that case, the defendant agreed to buy a business from the claimant, subject to the approval of the defendant's shareholders. The defendant and its directors agreed to use their best endeavours to obtain the shareholders' approval. In the event, the market moved against the defendant so that the agreement was no longer financially attractive. The directors issued circulars to the shareholders saying that the transaction was not recommended (this despite their obligation to use their best endeavours to get the shareholders to approve it).

The claimant, naturally enough, sued, alleging breach of the obligation to use best endeavours to obtain the shareholders' approval. The court, however, said that the claimant must have been aware that the directors of the defendant were under a duty to give proper advice to the defendant and its shareholders and that there could be no breach of the obligation if the directors gave proper advice: *"On its true construction the "best endeavours" covenant did not oblige the directors ... to give advice which they genuinely believed to be bad advice."*

One final rider that needs to be added is that the outcome that is to be achieved may affect the weight of the obligation. In **Little v Courage Limited [1995] 70 P&CR 469** the Court of Appeal said:

"An undertaking to use one's best endeavours to obtain planning permission or an export licence is sufficiently certain and is capable of being enforced. An undertaking to use one's best endeavours to agree, however, is no different from an undertaking to agree or to try to agree or to negotiate with a view to reaching agreement; all are equally uncertain and incapable of giving rise to an enforceable legal obligation."

If a "best endeavours" obligation is to be enforceable, therefore, it is necessary that the objective is identifiable and capable of being defined. If it is not, there may be no obligation at all.

Reasonable endeavours

Having discussed the "best endeavours" obligation, what have the English courts said about the term "reasonable endeavours"?

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In **UBH (Mechanical Services) Limited v Standard Life Assurance Co [1990] BCLC 895** reasonable endeavours were described as being “...*appreciably less than best endeavours*...”.

Therefore, in certain cases the expression “reasonable endeavours” may impose a very weak obligation.

It is clear that in judging what is required by a reasonable endeavours obligation, a party is entitled to have regard to its own interests, particularly its own financial interests (**Phillips Petroleum co UK Limited and Ors v Enron Europe Limited [1997] CLC 329**). Therefore a party should have done enough to satisfy “reasonable endeavours” by defending its position on the basis of its own interests (**P&O Property Holdings Limited and Ors v Norwich Union Life Insurance Society [1993] EGCS 69** and **Yewbelle v London Green Developments [2006] EWHC 3166**). In other words, provided it is not in a person’s own interests to comply with an obligation to use its “reasonable endeavours” to do something, then in some circumstances at least it may not have to do so.

However, in the recent case of **Rhodia International Holdings Ltd and anor v Huntsman International LLC [2007] EWHC 292** it was held that where a contract specifies that certain steps have to be taken by a party as part of exercising reasonable endeavours, those steps will have to be taken even if they involve sacrificing that party’s commercial interests.

All reasonable endeavours

It has generally been thought by English lawyers that the expression “all reasonable endeavours” imposes an obligation somewhere between “reasonable endeavours” and “best endeavours”.

In the **Rhodia** case, the judge made a general comment that an obligation to use reasonable endeavours was less stringent than an obligation to use best endeavours. He went on to note that:

“...there may be a number of reasonable courses which could be taken in a given situation to achieve a particular aim. An obligation to use reasonable endeavours to achieve the aim probably only requires a party to take one reasonable course, not all of them, whereas an obligation to use best endeavours probably requires a party to take all the reasonable courses he can. In that context, it may well be that an obligation to use all reasonable endeavours equates with using best endeavours.”

Commercially reasonable endeavours

One may see the expression “**commercially reasonable endeavours**” in a contract. This particular expression does not appear to have been examined by the English courts, but it is generally assumed to have the same meaning as “reasonable endeavours”.

Analysis

The cases mentioned above highlight some very important issues for anyone involved in drafting or negotiating contracts in which qualified obligations are used.

Many people seem to think that a “best endeavours” obligation provides a considerable degree of protection. However, in a number of the cases in which it has been discussed, an obligation to use best endeavours is actually no more than an obligation to do what is reasonable in the circumstances. If the party entering into the obligation also has conflicting obligations to third parties, they may overrule the contractual obligation. Also, extraneous circumstances may make it acceptable to do nothing at all or even to take steps that will actually defeat the purpose of the obligation. Lastly, if the intended outcome cannot be certainly identified, then there may be no obligation at all.

The term “reasonable endeavours” can mean a considerably lower level of obligation than “best endeavours”, so that if a party that has undertaken to use its reasonable endeavours to do something can say that it would not have been in its best interests to do it, it is possible that it does not have to do anything at all. However, this will not apply to steps that are expressly stated to constitute part of reasonable endeavours, even if those steps run contrary to the party’s best interests.

Drafting recommendations

There are a number of things to consider:

- If performance of an obligation is important to you, try to make sure that it is an absolute obligation (i.e. it is not qualified with either “best endeavours” or “reasonable endeavours”).
- If you are the party actually entering into the obligation, then of course you may find it helpful if the obligation is only one to use your “reasonable endeavours”.
- Always bear in mind that a reasonable endeavours or best endeavours obligation may be qualified by later events that neither you nor the other party have thought of.
- In service contracts, if you are the party receiving the service, beware of relying on a “reasonable endeavours” obligation to provide the service. If it subsequently becomes uneconomic for the supplier to continue to provide the service, then the “reasonable endeavours” reference may mean that the supplier may be able to argue that it is entitled to stop doing so!

Example 1

If the other party refuses to enter into an absolute obligation, then rather than relying on a simple term such as “best endeavours” you should use a defined term like (for example) “reasonable efforts” and should specify in the agreement exactly what this is supposed to mean. For example, you could use something along the lines of the following:

*Where this agreement refers to a party using its “**reasonable efforts**”, this means making every effort that the party concerned can, consistent with the objective to be achieved (and taking into account any time scale within which it is aimed to achieve the objective concerned). Reasonable efforts must at least include:*

- (a) *The allocation and use of resource (in manpower, financial and other terms) sufficient to achieve the relevant objective within any applicable time scale;*
- (b) *Taking all positive steps that are necessary to achieve the relevant objective;*
- (c) *Obtaining any further information necessary to enable the achievement of the objective;*
- (d) *Co-operating with others to the extent necessary to achieve the objective; and*
- (e) *If the first attempt to achieve the relevant objective is not successful, making further attempts as are reasonable so as to achieve it until such point as it becomes apparent that it is impossible to achieve the objective concerned.*

No drafting solution of this form could ever be perfect (clearly an absolute obligation would be better) but the wording above is considerably better than merely saying “will use its best endeavours” to achieve the objective.

Example 2

A licensee may be required to use “commercially reasonable efforts” with respect to the development of a compound that has been licensed to it, and/or the commercialisation of the product that is ultimately developed. A method that is commonly used to define “commercially reasonable efforts” is to define the efforts by reference to standards adopted by a third party. For example:

“Commercially reasonable efforts” means, with respect to the:

- (a) *Preclinical or clinical development of a Licensed Compound; and*
- (b) *Exploitation (including without limitation manufacturing, using, importing, exporting, distributing, marketing or otherwise disposing of) of a Licensed Product,*

such efforts and resources customarily used by a Major Pharmaceutical Company for therapeutics with a similar commercial potential and at a similar stage of development, having regard to all relevant factors including (without limitation):

- 1. Their safety and efficacy characteristics;*
- 2. Their cost and complexity of development;*
- 3. The competitiveness of alternative products;*
- 4. The actual or anticipated nature and extent of their market exclusivity (including without limitation patent coverage and regulatory exclusivity);*
- 5. The likelihood of regulatory approval;*
- 6. Their expected profitability.*

In the example above, "Major Pharmaceutical Company" might be defined to be a top twenty pharmaceutical company (based on global sales).

Daniel Pavin and Dr Matthew Jones

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In brief

EPLA - update on developments [Back to contents](#)

In a confidential document leaked from the European Parliament last month, the Legal Service of the European Parliament delivered an interim opinion on the legality of Member States' participation in the EPLA. The Legal Service held such participation to be contrary to current EU legislation (including IP enforcement and jurisdictional legislation). It concluded that, where "common rules" had been adopted by Member States in any particular area, the Member States of the EU were not then free to enter into further agreements that contradicted such "common rules". Therefore, Member States were not free to enter into the EPLA without breaching certain obligations under the EC Treaty and other EU legislation as the matters governed by the EPLA were within the exclusive competence of the Community. Prima facie this places a further significant hurdle before those Member States seeking to endorse the EPLA. However, nothing is that simple in the European legislature and one suspects that it is certainly not a death knell for the EPLA as implied by some. Rather, the European Commission has now taken the next move in this complex political dance as described below.

In a recent speech at the European Parliament's Joint Legal Affairs Committee, Commissioner McCreevey set out the initiatives that the Commission would be pursuing this year and one of its priorities remains the reform of the patent system within Europe. The Commission has been asked (by the Spring European Council) to produce a report setting out its future strategy for patents. It is widely thought that the publication of this report will be delayed until the French elections are complete, but Commissioner McCreevey gave a snapshot of its contents within his speech. He further called on all interested parties to compromise in order to change a system whereby enforcement has to be conducted nation by nation exposing litigants to the risk of diverging results in different Member States. The patent strategy document (which it seems Commissioner McCreevey has had significant input into) will address both the main issues of the Community Patent and the European Patent Litigation Agreement and also subsidiary (termed "flanking" by Commissioner McCreevey) measures including technology transfer, patent litigation insurance, and enforcement on an international level.

Dr Gareth Morgan

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Employee inventions – who owns them? [Back to contents](#)

The law says that an employee's invention shall belong to the employer if it was made in the course of:

- the normal duties of the employee, or
- duties falling outside his/her normal duties, but specifically assigned to him/her and
- an invention might reasonably be expected to result from the carrying out of his/her duties.

In the recent case of **Liffe Administration & Management v (1) Pavel Pinkava (2) De Novo Markets Limited [2007] EWCA Civ 217**, the employer argued that the meaning of 'normal duties' includes those imposed by a contract of employment and those which may evolve over time. The employee argued that 'normal duties' doesn't extend past every day activities – evolution of contractual duties is irrelevant because it goes past what's normally expected of you. In that case, the employer won. The employee's work was not specifically assigned because it had become a normal part of the job. The normal duties at the time included a responsibility to consider and devise the products at issue in the case. Given that particular employee's skill and expertise, it was reasonable to expect that he may have come up with an invention, even if the specific invention had not been expected. By definition, it is difficult to 'expect' an invention to result from research, because in order to be patentable, it must be novel and non-obvious. So, if an employee were asked to innovate, the results of such innovation would belong to the employer.

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In conclusion, in deciding if an invention arose out of an employee's employment the following factors should be considered:

- You can't just refer to the contract of employment because duties naturally evolve with time – the contract will not necessarily include all the duties
- As employee's skills develop, the nature of the job may change and different duties are expected
- The qualities of the particular employee are relevant
- The fact the employee hadn't been asked to do what was achieved is irrelevant

Jocelyn Whinney

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France legislates on biosimilar products [Back to contents](#)

France has finally implemented into French Law the provisions of EU Directive N° 2004/27/EC of 31 March 2004 related to pharmaceutical products (the New Community Code Directive).

The French Parliament has also enacted a new law (Law N° 2007-248 of 26 February 2007). This implements into French law the provisions on similar bio products from the New Community Code Directive.

Article 4 of the new French law on similar bio products introduces a definition of biologically similar product into the French Health Code. Article 4 enacts the provisions in clauses 10.2 (b) and 10.4 of the new Community Code Directive. However, the French Government has yet to enact regulatory provisions (decree) setting out the type of pre-clinical tests and clinical trials which will be required prior to approval being granted for any bio similar product. Under French constitutional and administrative laws article 4 is not applicable until publication of such decrees.

Olivier de Chazeaux

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Regulatory review

The new Code of Practice for the Pharmaceutical Industry 2006: one year on

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The new UK Code of Practice for the Pharmaceutical Industry 2006 (the "2006 Code") came into force on 1 January 2005, with transitional provisions applying until the end of April 2006. The 2006 Code covers the promotion of prescription-only medicines to healthcare professionals and appropriate administrative staff, as well as setting out standards for the provision of information on such medicines to patients and the public. It replaced the 2003 version (the "2003 Code").

The 2006 Code was the result of a major review by the Association of the British Pharmaceutical Industry (the "ABPI") and its members. The review included wide consultation with a range of interested parties: the Medicines and Healthcare products Regulatory Agency, the Department of Health, healthcare professionals and consumers.

The 2006 Code included a number of changes. This article examines recent cases under the 2006 Code which relate to two of those changes, and looks at the guidance in those cases from the body which operates the 2006 Code, the Prescription Medicines Code of Practice Authority (the "PMCPA").

Relationships with patient groups

One of the aims of the 2006 Code is to increase the transparency of relationships between pharmaceutical companies and patient groups. Pharmaceutical companies must declare any sponsorship of materials produced by a patient group, and must ensure compliance with the prohibition on advertising prescription only medicines to the public.

The supplementary information to Clause 20.3 of the 2006 Code states that:

*"Any involvement a pharmaceutical company has with a patient organisation must be declared and transparent. Companies must make public by means of information on their websites **or** in their annual report a list of all patient organisations to which they provide financial support. This might include sponsoring materials and meetings."*
[Emphasis added]

Two recent cases have given further guidance on the obligation for a pharmaceutical company to make public a list of patient organisations to which they provide financial support. In each case, it was alleged that the pharmaceutical company had delayed disclosing details of their financial report until their 2007 annual reports. In both cases the PMCPA found that the companies had not breached the 2006 Code.

Which method of disclosure should be used?

The PMCPA emphasised that the two methods for disclosure provided in the supplementary information were alternatives, and the timeframe for disclosure would be different in each case.

If a company elected to disclose information on its website, it would need to keep that information as up-to-date as possible. Disclosure through an annual report would, of course, be retrospective. This was an inevitable consequence of the way in which the supplementary information was worded.

Disclosure via a website

On the basis that the transitional period for the 2006 Code expired at the end of April 2006, the PMCPA considered that, where a company elected to disclose through a website, the site should have been operational by 1 May 2006. It should include details of all involvements with patient organisations entered into after 1 January 2006 (when the new 2006 Code came into force) and any earlier arrangements which are still in place.

Disclosure in an annual report

Where a company elects to follow this route and publishes its annual report on a calendar year basis, the guidance from the PMCPA is that the information about involvement with patient organisations should appear for the first time in the annual report covering 1 January to 31 December 2006, and is therefore published in 2007. Where the

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company does not use a calendar year basis for its annual report, the 2005/2006 annual report should be the first to include details of involvement with patient organisations. As for disclosure through a website, the first annual report should include details of all involvements with patient organisations entered into after 1 January 2006 and any earlier arrangements which are still in place after 1 January 2006.

Responding to enquiries on involvement with patient organisations

The PMCPA noted that companies should, regardless of their chosen disclosure route, be prepared to make available up-to-date information about involvement with patient organisations at any time in response to enquiries.

Medical and educational goods and services, and promotional aids

The 2003 Code permitted pharmaceutical companies to provide medical and educational goods and services which enhanced patient care or which benefited the NHS. The 2006 Code went further to state that goods and services which benefit the NHS must also maintain patient care. Medical and educational goods and services must not be supplied in such a way as to be an inducement to prescribe, supply, administer, recommend or buy any medicine. The 2006 Code gives more guidance on the role of sales representatives in the provision of medical and educational goods and services: any role they do have should not be linked in any way to the promotion of products.

The 2006 Code permits companies to provide gifts in the form of promotional aids, provided that they are (i) inexpensive (at a cost to the company of no more than £6 excluding VAT), (ii) of a similar perceived value to the recipient, and (iii) relevant to the practice of the recipient's profession. Requirement (ii) was introduced by the 2006 Code. Promotional aids should not be used as an inducement for a sales representative to gain an interview.

A case decided under the 2003 Code during the transitional period for the 2006 Code highlights the importance of ensuring that the provision of medical and educational goods is clearly differentiated from the provision of promotional aids. The PMCPA noted the references in both the 2003 and 2006 Code to the option for companies to use staff other than sales representatives to provide medical and educational goods and services. In this case, the PMCPA felt that the sales representatives were inextricably linked to the provision and distribution of the educational goods: they chose which doctors were offered the goods, they signed the letters offering the goods, and also offered to deliver them. The PMCPA found that there was a breach of clause 18.1 of the 2003 Code (which is now 18.4 of the 2006 Code).

Stethoscopes and memory sticks

In a case under the 2006 Code, a stethoscope was offered as a promotional aid. It was clearly relevant to the practice of medicine, and cost the pharmaceutical company less than £6. The question arose as to what the perceived value of the stethoscope might be to the recipient. The PMCPA found that, although some stethoscopes could cost considerably more than £6, there were many which do not. They also accepted that the stethoscope on offer in this case did not appear, from the photograph provided to the intended recipients, to be an expensive one.

A second case under the 2006 Code considered the offer of a memory stick as a promotional aid. While not specifically asked to rule on the question of whether this was appropriate as a promotional aid, the PMCPA did not express the view that it was an inappropriate promotional aid. A ruling under the 2003 Code considered the provision of a memory stick as a promotional aid and did not find it to be a breach of the Code.

This recent case did, however, highlight the importance of ensuring that a reply paid card offering the promotional aid makes it clear that, although a sales representative will deliver the item, there is no obligation to grant them an interview. This accords with the provision in both the 2003 and 2006 Code which prohibits the use of an inducement by a sales representative to gain an interview with a healthcare professional. No breach of the 2006 Code was ruled.

Summary

Pharmaceutical companies bound by the 2006 Code should ensure that:

- they comply with their obligations to disclose their involvement with patient groups, either through a website or through their annual report;
- they are able to respond to any ad hoc enquiries about their involvement with patient groups by providing up-to-date information;

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- they consider carefully the perceived value of a promotional aid to the recipient and ensure that it is similar to the actual cost to the company (which in turn must be no more than £6 excluding VAT); and
- the role of any sales representatives in providing, delivering or demonstrating any medical or educational goods or services is not linked in any way to the promotion of a product. The 2006 Code states that a representative should not carry out both activities in the same visit to a healthcare professional.

Tim Worden

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Guest Article

“IP Valuation in pharmaceuticals and biotech” [Back to contents](#)

Robust valuation of intellectual property (IP) is critical to the success of a pharmaceuticals and life sciences business at all stages of its development:

- The value of IP is usually a major consideration in Mergers and Acquisition and licensing activity
- Understanding the value of your IP can help you prioritise projects and therefore assign appropriate resources to individual projects
- Valuation of IP is required at all stages of fund raising
- Valuation of IP for financial reporting purposes

IP valuation forms part of the financial reporting requirements for companies reporting under US GAAP and International Financial Reporting Standards (IFRS) regarding acquisitions. This requires a rigorous process to identify and value all intangible assets including the value of R&D pipelines.

This article aims to explain the various valuation techniques and how these can be applied to the pharmaceuticals and biotech industries.

1. Valuation methods

Most intangible assets generate premium returns for the business that owns them, either through an increase in revenues or through a reduction in costs. All valuation methods focus on capturing the value of these premium returns, but some are more suited than others to different types of IP. The principal methods of valuation which are deemed to be acceptable to value intellectual property for financial statement purposes are as follows:

- Income approach
- Market approach
- Cost approach

Each of these methods, together with their relevance in the evaluation of pharmaceuticals and biotech projects, is discussed briefly below.

2. Income approach

This is the most common approach for intangibles since it captures expected future returns to the owner and can be used to estimate values for unique assets. There are several variations of the income approach which are either based on cash flows or earnings generated by the intangible asset or are based on the costs saved by the intangible asset:

- Excess earnings
- Premium pricing method
- Cost savings method
- Royalty savings method

Excess earnings method

The excess earnings method determines the value of the IP by calculating the present value of the incremental after-tax cash flows attributable only to that intangible asset. The approach considers the excess returns that the business makes and then deducts the contribution to returns that other pieces of IP make in order to identify the excess returns arising from the IP under evaluation.

It is important, if using this method, to ensure that the excess earnings identified are specifically attributable to the intangible asset in question and not to some other factors such as an efficient production facility or distribution network that relates to the business as a whole.

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This method is the most suitable for evaluating pharmaceutical R&D projects and section 3 below describes how this approach can be tailored to the evaluation of pharmaceutical R&D.

Premium pricing method

The premium pricing method is a variation on the excess profits method and is often used to value brands in the consumer products sector where it is common for a branded product to be more expensive than an unbranded equivalent. The value of this additional revenue projected over the life of the brand, net of the marketing and other brand support costs incurred to achieve this revenue, and discounted to the present day, provide a value for the brand. This can be relevant to pharmaceuticals for products where brand has a significant value (for example, in the branded generic or over-the-counter markets).

Cost savings method

The cost savings method is fairly self-explanatory and values the asset by calculating the present value of the cost savings that the business expects to make as a result of owning the asset. This is usually as a result of an efficient process or secret technology.

Whilst a business can usually calculate the costs it has saved since it introduced the new process, it can be more difficult to estimate whether a third party would save more or less costs if they introduced the same technology to their own business. This can be of use to evaluate pharmaceutical production or development "know how" where the asset generates measurable cost savings. However, it is of limited use in evaluating pharmaceutical R&D where the greatest proportion of value arises from future income streams.

Royalty savings method

The royalty saving method is based on the principle that, if the business did not own the asset, it would have to in-license it in order to earn the returns that it is earning. Alternatively the business could out-license the asset if it did not wish to use it. The value of the asset is calculated based on the present value of the royalty stream that the business is saving by owning the asset.

Whilst this method is popular, its major drawback is that details of royalty rates are rarely made public. An appropriate rate can however be estimated by considering the effective premium profits that are earned by exploiting the asset in question and remembering that each party to a licensing agreement needs to earn a commercial return on their investment. This can be of use to evaluate pharmaceutical production or development technologies where the alternative would be to in-license the technology. It can be of use when evaluating pharmaceutical projects where comparable royalty data can be used (such as drug delivery technologies).

Market approach

The market approach values the asset based on comparison with sales of similar assets. The transaction price, as a ratio of an asset attribute such as sales, is used to derive a market multiple. This market multiple is then applied to the attribute of the asset being valued to indicate the value of the subject asset. As many multiples as possible should be derived e.g. sales, EBITDA, EBIT. In an ideal world this is the best method as a true "market value" is available.

In practice, however, the world is not ideal and it can be difficult to find sufficiently detailed publicly available information on sales of similar assets. Nonetheless, this can be of use when valuing pharmaceutical companies where comparable company data is readily available and serves as a good cross check of results from other methods.

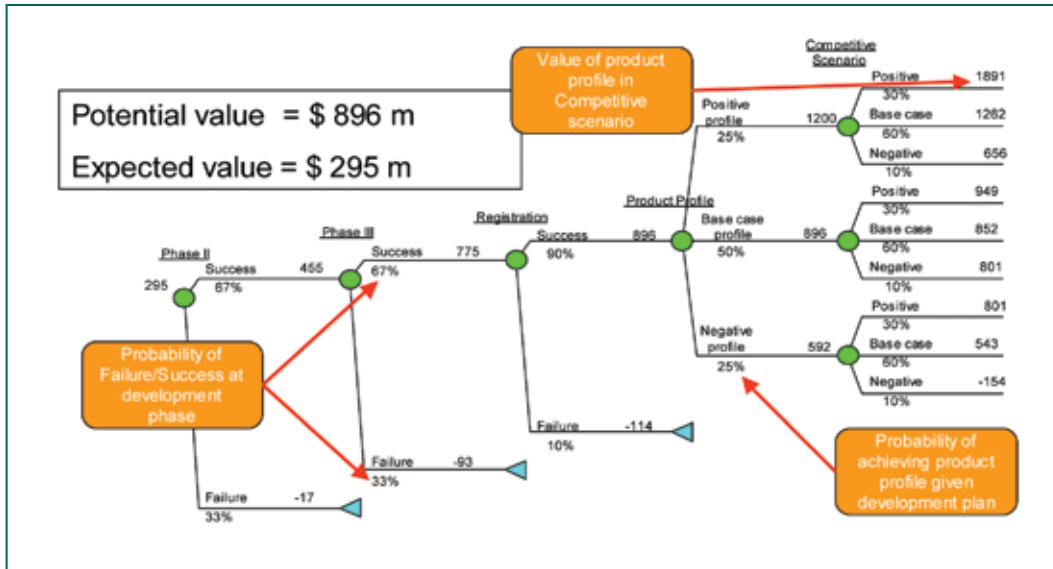
3. Cost approach

The cost approach values an intangible asset by accumulating the costs that would currently be required to replace the asset. The premise of the cost approach is that an investor would pay no more to purchase the asset than would be paid to reproduce the asset. We include this for completeness though it is rarely used to evaluate pharmaceutical R&D where spent costs are not an indicator of future value.

In conclusion, PricewaterhouseCoopers find that the income approach is usually the most relevant to valuing intangible assets in the pharmaceuticals industry with the market approach, royalty savings, or cost savings approach used as a cross check if relevant data can be obtained. The application of the income approach to the pharmaceutical industry will now be explored in more detail.

4. Exploring the income approach - expected cash flow technique

The most common income-based approach to valuing pharmaceutical development investments is to determine the expected Net Present Value (eNPV) of the investment using a decision tree approach. Decision trees provide a convenient approach for valuing investments around which there is significant uncertainty about the future outcome and associated cashflows. They allow the value of different outcome scenarios to be explicitly captured and then combined using probabilities for different outcomes occurring to produce an overall average or expected value for an investment. This makes the decision tree approach highly suited to the evaluation of development projects where projects can potentially fail at any phase of development and where the commercial value is still uncertain.



Source: PricewaterhouseCoopers LLP

Decision Tree for a drug in development

PricewaterhouseCoopers recommend developing two or three scenarios for each of the major uncertainties (such as product profile or commercial environment). For each scenario, cashflows are developed based on future costs and revenues. Each branch of the tree will then generate a separate set of cashflows that are used to calculate the net present value (NPV) of each scenario – the example above will generate 12 scenarios. The NPV of an endpoint is then multiplied by the probabilities of each branch in order to generate an expected value, or eNPV of the technology. Although decision trees can be complex, PwC recommend keeping them as simple as possible but also as comprehensive as possible whilst staying at a high level. This is so that the decision tree is easily communicated to others.

Indeed this decision-tree based approach is now considered best practice in the US, particularly in the pharmaceutical sector. The American Institute of Certified Public Accountants have issued a Practice Aid which considers approaches to be adopted when valuing in-process R&D in the pharmaceuticals and technology sectors.

5. Robust valuation – critical success factors

There are a number of critical success factors for effective project evaluation and portfolio management:

- Mind the external view. The valuation approach should be broadly similar to that employed by external analysts and financiers.
- Account for uncertainty directly. Qualifying uncertainty can be difficult, but try to finesse it. It may feel easier to include all the risk in the discount rate used to calculate the NPV or to use merely qualitative measures but attempting to quantify risk at each step will lead to more robust results.
- Be consistent. Although every project is unique, employing a similar valuation approach to all projects will result in a more robust valuation. Building complex custom models or searching for the perfect project-specific discount rate is time-consuming and makes objective comparison more difficult.
- Ask why. The role of a reviewer is not just to check assumptions but also to challenge the underlying thinking.

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- Be balanced. It would be impossible for a model to include all the aspects of value and there is value in remaining high-level and consistent such that the assumptions can be easily challenged rather than complex and customised where there is the risk that the valuation ends up as a black box.

6. Choosing the appropriate valuation method

Best practice when valuing any asset is to use as many methods as possible to make the conclusion on value robust. However, some of the above methods are more suitable for certain pharmaceutical assets than others and there is always the practical limitation of what information is available.

A robust valuation model can greatly assist the IP strategy and commercialisation strategy of a new pharmaceuticals project. In this article, we have outlined a method for doing this that is employed by leading edge pharmaceutical companies. This process can be used for smaller ventures and may help to evaluate the value of a project and the key uncertainties driving value.

An earlier version of this article first appeared in the Business Development & Licensing Journal published by the Pharmaceutical Licensing Group (PLG) Ltd.

***Jo Pisani** is a Director in the Pharmaceuticals and Healthcare team at PricewaterhouseCoopers LLP. Her team focuses on providing valuation services and portfolio management to the pharmaceuticals and biotech industry for decisionmaking, deal due diligence, and financial reporting purposes; and strategy validation and business plan review services.*

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Life sciences and healthcare events

News from the LSH Group [Back to contents](#)

Dr Gareth Morgan attended the [BioTrinity 2007](#) on **27-28 March 2007**, at the Oxford Belfry Hotel, Oxford, UK

Nigel Stoate and Simon Cohen spoke on "*Interpretation of Patents post Kirin-Amgen*" at the [Intellectual Property Law and Practice 2007](#), Lexis Nexis Butterworths conference on 27 March in London

Simon Walker spoke on "*The private M&A process – tips and strategies for a marriage made in heaven*" at the [C5 conference Life Sciences M&A and Strategic Alliances](#) at Millennium Hotel, Knightsbridge, London on 29-30 March

Partner Daniel Pavin and other members of Taylor Wessing's Life Sciences & Healthcare team have written a chapter entitled "Expansion: European and International Considerations for Biotechnology Companies" in the American Bar Association's new publication "Biotechnology and the Law". The chapter covers regulatory and legal issues relevant to a biotechnology company expanding into the European market. If you would like to request a copy of the chapter, please contact Daniel Pavin on +44 (0) 20 7300 7000

Further details of the publication are available from the [ABA](#) website and from [Amazon.com](#)

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Partner Nigel Stoate is speaking on "*Key legal issues and strategy for pharmaceutical product launch in Europe*" at the Visiongain - [5th Annual Pricing and Reimbursement Conference](#) on 10-12 April 2007

Taylor Wessing is sponsoring "[Life Science Alliances World](#)" on 16 to 18 April 2007 at the Victoria Park Plaza Hotel in London. One of our partners, Daniel Pavin, will be speaking on 'Industry trends and their effect on licence and collaboration agreement terms'. If you would like to find out more about this event please contact [Daniel Pavin](#)

Dr Malcolm Bates and Daniel Pavin are attending [Bio2007](#) on 6-9 May 2007. Dr Malcolm Bates is speaking with Stephane Boissel, Executive Vice President and CFO, Innate Pharma SA and Paul Connuck, Partner, Kramer Levin Naftalis & Frankel LLP on Monday 7 at 11am in room 258c on "Achieving "Win/Win" in Pharma: Biotech Global Collaboration Agreements

Jason Rawkins and Nigel Stoate are speaking at the Hawksmere conference "[Intellectual Property and the inhouse lawyer](#)" on 15-17 May

Taylor Wessing are sponsors of the [European Partnering and Investment Conference 2007](#) on June 21 at the Cumberland Hotel London and partner Simon Walker is speaking on mergers and acquisitions in the biotechnology industry

Daniel Pavin is speaking at the [C5 conference Optimising Clinical Trial Outsourcing and Creating Strategic Partnerships](#) on 14-15 June 2007

Marjan Noor is speaking at the [C5 Conference EU Pharma Law and Regulation](#) on 18-19 September 2007

Nigel Stoate and Simon Cohen are speaking at the [SMI Pharmaceutical Portfolio & Life-Cycle Management](#) Conference 27/28 June

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Open minds, closed deals

Taylor Wessing is top rated in the Pharmaceuticals and Biotechnology section of the UK Legal 500 2006 and in the IP and commercial and partnering sections of PLC's 2006/7 Life Sciences Handbook. Taylor Wessing is also top rated for venture capital work in the UK Legal 500 2006 and has been voted "Technology Law Firm of the Year" at the UK Technology Innovation and Growth Awards 2007.

Recent Life Science Deals

<h3>Oxford BioMedica</h3> <p>Taylor Wessing advised Oxford BioMedica (LSE: OXB) and sanofi-aventis (EURONEXT: SAN; NYSE: SNY) on an exclusive global licensing agreement to develop and commercialise TroVax® for the treatment and prevention of cancers.</p>	<h3>Innate Pharma</h3> <p>Advising Innate Pharma on a major expansion of its partnership with Novo Nordisk in respect of natural killer cells. The deal also involved a €10 million investment by Novo Nordisk in new Innate Pharma equity and support for its IPO</p>	<h3>Vétoquinol</h3> <p>€250 million</p> <p>Advised the underwriter Oddo Corporate Finance on the IPO on the French Stock Exchange (Eurolist by Euronext) of animal health company Vétoquinol</p>
<h3>Bayer HealthCare</h3> <p>Advised Bayer HealthCare AG on the divestment of the production of animal health biological vaccines to Intervet, a subsidiary of Akzo Nobel</p>	<h3>Apax Partners France & Merlin Biosciences</h3> <p>\$35 million</p> <p>Advised Apax Partners France and Merlin Biosciences in a \$35 million private equity financing led by Burrill and Company in a US biotech company specializing in the development of innovative sight-saving therapeutics for chronic retinal diseases</p>	<h3>Neurotech Pharmaceuticals Inc.</h3> <p>Advised Neurotech France SA and its existing investors, including Apax Partners France, Merlin Biosciences, Atlas Venture, Mayflower (3i group), Avida Group and Alpha Associates in completing a flip transaction into the US, leading to the incorporation of Neurotech Pharmaceuticals, Inc.</p>
<h3>Debiopharm Group</h3> <p>Advised Debiopharm Group on an exclusive agreement with Cambridge Antibody Technology to develop and market SC-1 for gastric carcinomas</p>	<h3>UCB</h3> <p>Advising UCB on an expanded product licence agreement for Xyrem® (sodium oxybate) with Jazz Pharmaceuticals, Inc. Under the agreement, UCB obtains the right to commercialise Xyrem for the treatment of fibromyalgia syndrome</p>	<h3>Faust Pharmaceuticals</h3> <p>€9 million</p> <p>Advised the company and syndicate on the bridge financing of Faust Pharmaceuticals, a French clinical stage therapeutics company focused on the nervous system</p>

For more information on Taylor Wessing, please visit www.taylorwessing.com

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