

The newsletter of the Life Sciences Group



Welcome to the Winter/Spring issue of BioBrief. In this edition we discuss the latest developments on the Patent Box Regime, the US case of AMP v USPTO, the right of first refusal and the BIS's strategy to boost the UK Life Sciences Industry.

BOXED IN UPDATE

The Government has published its response to the June 2011 consultation in relation to certain proposed provisions of the new Patent Box regime. The Government restates its objective of wanting to achieve the most competitive tax system in the G20, with the patent box regime being a fundamental part of achieving that objective. The revisions proposed as a result of the consultation process are largely positive in extending the scope of relief obtainable. Further proposals have been made to overcome or address certain feedback. The response deadline in relation to these further proposals is 10 February 2012.

Summary of Patent Box proposals

The Patent Box provides for a reduction in corporation tax to 10% on **profits** attributable to 'qualifying IP'. Any company with qualifying IP will be entitled to take advantage of the lower rate of corporation tax, including patent owners and exclusive licences. The latest publication focuses on the following main areas:

- Definition of 'Qualifying IP' and in particular whether the definition was broad enough or should be extended;
- Definition of 'Qualifying Income' and whether income should be linked to specific patents or to products/ licences more generally. The consultation also looked at whether the 'look-back' period was sufficient and requested feedback on the proposed approach for calculation of patent profit embedded in service income;
- Use of the formulaic approach for calculating attributable profit and the inclusion of R&D costs;
- Suggestions for anti-avoidance rules.

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Some of these changes in approach are discussed further below.

Definition of Qualifying IP

Following the consultation the Government is proposing to extend the breadth of qualifying IP covered. Qualifying IP will now additionally include:

- EU patents more generally (rather than just patents granted by the EPO and UK patent office). The government is proposing to list the EU Member States that it considers have comparable patent criteria to those used in the EPO and UK patent offices. Patents granted by these listed EU Member States will qualify for relief;
- Ability for companies using qualifying IP by virtue of intra-group transfers or licences to claim relief. The government proposes to amend the rules to make it easier for group companies to qualify where, for example qualifying IP is held centrally;
- Existing IP (for example existing patents) as well as newly commercialised IP will be included within the qualifying IP definition but the patent box will be phased in over 5 years in order to minimise the impact on tax receipts.

Calculation of benefits

The previous proposals provided a divisionalisation rule which allowed companies to use an alternative allocation of qualifying and non-qualifying income compared to the standard pro-rata allocation. The Government is proposing that this should continue but that to simplify application for the benefit, a streaming approach is used rather than a transfer pricing methodology. Companies will be able to allocate profits to the income streams they receive on a 'just and reasonable' basis.

The full rate of corporation tax remains payable on profits attributable to routine activities. This level is calculated through a mark-up on certain defined costs. Rather than introducing a variable rate, the Government has reduced the mark-up from 15% to 10% and also excluded R&D expenses from the costs marked-up. This should increase the amount of profit eligible for patent box relief.

New rules have also been proposed in relation to allocation of profits between marketing (brand use) and genuine patent use.

Anti-avoidance methods

The Government is proposing a targeted anti-avoidance rule (TAAR) for the patent box. The aim is to target companies seeking to obtain an artificial tax advantage by inflating their patent box deduction.

In general

In general the changes being proposed appear favourable particularly in terms of extending the scope of qualifying IP. The Government has adopted an approach which aims at making application of the regime easier for smaller companies whilst leaving some flexibility in other areas (for example in relation to application of the divisionalisation rule).

DIAGNOSTIC METHODS UNPATENTABLE

During 2011, the US Federal Circuit Court of Appeal gave judgment in the case of *Association for Molecular Pathology v USPTO* (Fed. Cir. 2011), 29 July 2011. In summary, the claims of the patent related to (a) an isolated DNA coding for certain polypeptide(s); (b) a method for detecting an alteration to a particular gene; and (c) a method for screening potential therapeutic agents.

Under previous US case law, the purification of a natural product is not patentable. In order for the outcome of the purification process to be patented it has to possess markedly different characteristics from the natural product. In the first instance the judge held that the isolated DNA was not substantially different from the wild-type DNA and therefore it was not different enough to be patentable. The first instance judge also went on to find the method for detection and method for screening claims as unpatentable, mainly because both claims were directed at "analysing" and sought to patent a basic scientific principle.

The Court of Appeal judgment was split. All three judges agreed on whether genetic diagnostic and screening methods were patentable. In relation to the isolated DNA sequence, the three judges used different approaches in analysing patentability.

(a) Isolated DNA sequences

The majority of the Court of Appeal accepted that in order for a DNA sequence to be patentable there had to be some form of distinction between the 'product of nature' and the 'human-made' sequence (following *Funk Brothers Seed Co. v Kalo Inoculant Co.* 333 US 127 (1948) and *Diamond v Chakrabarty* 447 US 303 (1980)). Hence isolation per se was not sufficient to obtain patentability. However when Judge Lourie analysed the isolated DNA, he concluded that human intervention (including cleaving or synthesising a portion of DNA) imparted on that DNA a distinctive chemical identity. He also

added that isolated DNA molecules were distinct from their natural existence as part of a larger DNA molecule. This identity was therefore different from that held by native DNA. The fact that the end protein or protein fragment was the same was irrelevant to the test i.e. the exact sequence (or information being imparted) was irrelevant.

Judge Moore applied the same test but rather than looking at the actions performed in relation to the DNA, she examined the isolated DNA for a change in utility, for example an increase in utility as compared to nature. She did not accept that the physical changes alone involved in the creation of DNA were sufficient to find patentability. Judge Moore looked at both the cDNA claims and the more general isolated DNA sequence claims. In relation to cDNA, there was clearly a difference from the corresponding DNA sequence in nature. The cDNA sequence did not exist in nature and hence cDNA sequences had a distinctive name, character and use and therefore markedly different characteristics.

The analysis relating to isolated DNA i.e. not cDNA was more difficult and the Judge accepted that DNA sequences that had the same DNA bases as the natural gene presented a more difficult issue. She applied the same test i.e. whether there were differences in chemical structure and whether the differences in chemical structure between the isolated DNA and natural DNA imparted a new utility. The claimed DNA had been generated with different terminals not found in nature thus satisfying the first limb of the test and the end result enabled the primer to be used to detect the presence of gene mutation, thus satisfying the requirement for new utility. This ability or utility was as a result of human intervention and as a result provided patentability. Judge Moore did caution that the result was heavily dependent on the circumstances of the case – the existence of different truncations would not have been sufficient to grant patentability without the evidence of beneficial utility. In her view something more than chemical differences was required to find patentability.

The final judge, Judge Bryson dissented. He found that allowing patentability in the claimed sequences would have broad consequences. In his view the claimed sequences were not sufficiently distinct to be patentable. He concluded that this case was no different from the example given in *Chakrabarty*, where the only material change made to the claimed genes was as a result of the isolation and extraction of the genes from their natural environment. Judge Bryson stated that in analysing patentability the court should compare structure and utility, if the isolated gene had the same structure and functionality it would not be patentable. Judge Bryson did agree that claims to cDNA would be patentable, cDNA was not found in nature and therefore was sufficiently different. He did not agree with the other judges that claims to parts of the DNA sequence would be patentable, in his view these did not satisfy the test in *Chakrabarty*.

(b) Diagnostic method claims.

In relation to the diagnostic method claims, the judges agreed that the claims were not patentable because they amounted to abstract mental processes. So for example certain of the claims required comparison of the binding of two different DNA sequences (one from a cancer sample and one from a non-cancer sample). This in the court's view was nothing more than a comparison step between two different sequences. The court did say that a comparison step as part of an

overall process might be patentable, but in the case in issue the claims did not claim an entire process. The claims in issue did not include any element of determination or transformation, they simply involved comparison of binding between two sequences.

(c) Screening claims

The screening claims related to a comparison between the growth rates of certain cancer cell populations. Where a potential therapeutic agent affected that growth rate, in particular, where the growth rate of cells slowed, this would suggest that the therapeutic agent might be suitable for treating the relevant cancer. The Court of Appeal adopted the same test as used for analysing the diagnostic claims (see (b) above) i.e. did the claims include a transformation step? In this case the cells had to be grown in the presence or absence of the relevant agent. The growth rate of the cells then had to be determined and compared against host cell growth. Hence the claims included an element of manipulation and determination (of growth rate). These steps were central to the claimed process and as a result were patentable.

Summary

Claims to isolated DNA sequences remain patentable in the US although there is still a requirement to demonstrate some form of difference from the natural sequence. Exactly what needs to be demonstrated remains unclear but where there are both structural and functional differences, the DNA sequence is likely to be patentable.

In relation to diagnostic and screening claims, the test remains uncertain. Some form of transformation or part of an overall process is required. This transformation needs to be more than mere identification of a difference. Hence where there is some kind of computational requirement or comparison required, this test may be more easily satisfied than when the diagnostic or screening requires comparison alone.



RIGHT OF FIRST REFUSAL

Commercial contracts often contain clauses offering one or other party the first right to refusal in relation to some obligation, for example the right to obtain a product or to supply a product. In the case of *AstraZeneca UK Limited v Albermarle International Corporation and Albermarle Corporation* [2011] EWHC 1574 (Comm) 21 June 2011, Albermarle supplied AstraZeneca with the active ingredient ("DIP") for Diprivan. The contract for the supply also included a right of first refusal for Albermarle in relation to the supply of Propofol.

Right of first refusal clause:

"In the event that at any time BUYER reformulates or otherwise changes its Diprivan brand to substitute propofol for the PRODUCT, BUYER will so notify SELLER and will give SELLER the first opportunity and right of first refusal to supply propofol to BUYER under mutually acceptable terms and conditions."

AstraZeneca decided to switch supply to Propofol and offered Albermarle the right to tender for the supply. However following the tender, the business was awarded to a competitor (for amongst other reasons, price) and AstraZeneca argued that in doing so there was no breach of the term offering the right of first refusal.

AstraZeneca ran several arguments including that the right of first refusal clause was too uncertain to be valid. They also argued that all the right of first refusal required was the opportunity to participate in the tender process i.e. they had satisfied that requirement and therefore there was no breach. It was a right to negotiate and no more.

The UK High Court disagreed finding that there had been a breach of the clause providing for the right of first refusal. Such a term was not uncertain and it gave more than a right to negotiate. The judge found that 'first refusal' meant that Albermarle should be offered the opportunity to refuse the contract on the same terms as offered by the competitor i.e. it had to be given full disclosure of relevant terms in order to understand the terms it was entitled to match.

Having failed to win the argument in relation to the construction of the first right of refusal clause, AstraZeneca sought to argue that the limitation clause was effective and as a result Albermarle should be unable to claim loss of profits.

Limitation of liability claim:

"Claims: No claims by BUYER of any kind, whether as to the products delivered or for non-delivery of the products, or otherwise, shall be greater in amount than the purchase price of the product in respect of which such damages are claimed; and failure to give written notice of claim within sixty (60) days from the date of delivery, or in the case of non-delivery, from the date fixed for delivery, shall constitute a waiver by BUYER of all claims with respect thereto. In no case shall BUYER or SELLER be liable for loss of profits or incidental or consequential damages."

The High Court judge again disagreed finding that the limitation of loss of profits can not have been intended to exclude loss of profits for the breach of the right of first refusal clause. To find it effective in that way would remove any remedy from Albermarle and effectively render the clause of no commercial effect. He found instead that the clause limited loss of profits to loss of profits on the sale and purchase of DIP. The judge confirmed that interpretation of limitation clauses was a matter of construction and details of any breach by Albermarle were irrelevant to that construction; no presumption either way would be implied.

This case does not create any new law, but it does make it clear that in interpreting contracts, the court will look closely at the wording of the contract and construe that wording in a way which makes commercial sense. It also provides some clarity on the way in which a right of refusal may be interpreted by the courts and therefore the extent to which a provider of such a clause will have to go to satisfy it.

CLINICAL DISEASE STUDIES BACK AT THE HEART OF MEDICAL DISCOVERY

The Department for Business Innovation and Skills ("BIS") has published a Strategy for UK Life Sciences which focuses on measures to boost both investment and innovation within the UK Life Sciences Industry. The report recognises that the UK Life Sciences Industry is a vital part of the UK economy and as a result remains important to the growth of the UK economy more generally. The report is also a response to the rise in chronic conditions such as obesity, dementia and diabetes and focuses on a more patient-led approach to the industry and innovation.

The new strategy aims to promote the UK as a place to invest in life sciences and to enable cooperation between universities, hospitals and businesses to keep the UK at the forefront of medical research.

The new strategy is divided into the following main areas:

A fully integrated life sciences ecosystem

The UK life sciences industry needs to be the first choice for all members i.e. for researchers, clinicians, businesses and investors. BIS seeks to achieve this by placing clinical research at the heart of the NHS, enabling patients to participate and facilitating commercialisation. It also aims to support the UK life sciences industry internationally. In terms of actual substance BIS gives itself a series of actions to achieve its stated aims. These actions vary between set investment into either funds (for example the new Biomedical Catalyst Fund) or particular centres/ industry areas (for example investment into the CPRD) together with increased access to information and promotional activities.

Attracting, developing and rewarding talent.

BIS accepts that whilst the UK has a high concentration of research excellence it can be difficult to keep innovative individuals within the UK. Therefore it proposes a series of actions to provide a way

of maintaining research excellence within the UK and encouraging individuals to stay in the UK. BIS also notes that although SMEs and spin-out companies are often strong on science, there may be a lack of business and management skills which can make commercialisation/partnering of the science difficult. The proposals take the form of investment in the creation of clinical and non-clinical employment opportunities, provision of enhanced teaching standards and apprenticeship opportunities together with the development of an industry led mentoring programme.

Incentives for innovation

Following on from the Government's incentives to stimulate innovative growth within the UK, BIS provides additional actions to stimulate innovation within small high risk companies through provision of tax relief on investments, provision of investment to target the 'valley of death' and streamlining of the regulation process. The regulatory streamlining is aimed at simplifying the drug approval process and providing early access schemes for particularly innovative therapies or for treatments which address seriously debilitating conditions where there is no current treatment. BIS also recognises that innovative technologies may enable reduction in the regulatory requirements (for example through use of targeting technologies) and thus facilitate a reduction in the level of, for example, phase III clinical trials required.

Summary

There is a clear recognition and desire within the BIS proposals to develop ways of maintaining the UK's ability to provide a competitive life sciences offering. This is clearly very positive and hopefully welcomed by the life sciences industry. However whilst some of the proposals are clear and certain (for example investment of £180m in a new MRC/TSB Biomedical Catalyst Fund) others remain at the proposal or review stage. For example many smaller companies may have been hoping for more movement on the regulatory side to reduce the huge cost and time burden. Although the actions include review of the process and the commentary expresses a desire to look at ways of accessing drugs (and therefore potential revenue) at an early stage, the proposals still have a long way to go before they become reality and hence the short term impact on SMEs may be minimal.

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For further information please contact:

Kerry Sharp - Tel: 01865 813692 Email: kerry.sharp@manches.com

Manches is a leading law firm in Oxford, Reading and London. We advise clients on all areas of business law, including banking and asset finance, property, corporate, commercial litigation and dispute resolution, employment, intellectual property and technology law.

Manches LLP
9400 Garsington Road
Oxford Business Park
Oxford
OX4 2HN
Tel: +44 (0) 1865 722106
Fax: +44(0) 1865 201012

Manches LLP
Reading Bridge House
Reading Bridge
Reading
RG1 8LS
Tel: +44 (0) 118 982 2640
Fax: +44 (0) 118 982 2641

Manches LLP
Aldwych House
81 Aldwych
London
WC2B 4RP
Tel: +44 (0) 20 7404 4433
Fax: +44 (0) 20 7430 1133