Papers

Is 'evergreening' a cause for concern? A legal perspective

Scott Parker and Kevin Mooney

Date Received (in revised form): 7th August, 2007

Scott Parker
is a senior associate in the Intellectual Property Group at Simmons & Simmons. He specialises in contentious and non-contentious intellectual property matters and has a particular focus on pharmaceutical patient litigation.

Kevin Mooney
is a partner in the Intellectual Property Group at Simmons & Simmons. He also specialises in contentious and non-contentious intellectual property matters, focusing particularly on patent litigation in the pharmaceutical sector.
Simmons & Simmons is recognised worldwide as a pre-eminent law firm for the life sciences. It is Simmons & Simmons policy not to act for generic manufacturers in relation to patent expiry matters. For full CVs or further information, please see www.simmons-simmons.com.

Abstract

A number of fundamental principles (and misconceptions) of patent law and of the system for granting and enforcing patents lie at the heart of the so-called 'evergreening' debate on patent protection for pharmaceutical products. The purpose of this paper is to consider 'evergreening' from a legal perspective and to evaluate the extent to which the patent system operates to safeguard against the claimed abuses. In the authors' view the allegation that pharmaceutical companies have been able to delay substantially the entry of generic competition by 'evergreening' many of their patents simply does not reflect the reality and mischaracterises how the patent system operates in the context of technological innovation. A patent over an improvement does not restrict a generic company from launching a competitor of the originator product and, in the UK at least, the procedure and attitude of the court is conducive to the speedy and cost-effective challenge of 'weak' patents.

Journal of Commercial Biotechnology (2007) **13,** 235–243. doi:10.1057/palgrave.jcb.3050066

Keywords: *evergreening, incremental modification, strategic patenting*

INTRODUCTION

It is useful at the outset to attempt some definition of the terms used in the published papers on this subject. 'Evergreening' has become a pejorative term to mean that innovator pharmaceutical companies abuse the patent and regulatory systems to delay the legitimate entry of generic competition. 'Incrementally modified drugs' is most often used to describe variations (usually characterised by those complaining of 'evergreening' as 'minor') on existing pharmaceutical products such as new formulations, new crystalline forms, etc of the established product. 'Me-too drugs' is used to describe a drug of similar molecular structure used to treat the same condition as another, successful drug marketed by a competitor company. These last two expressions, however, are not used consistently and it is sometimes unclear whether the criticism of 'evergreening' in a particular instance is aimed at one or both of the above categories of development. In this paper, we use 'incrementally modified drugs' to cover both.

Debate on the economic, public health and policy aspects of 'evergreening' has tended to be polarised. In summary, critics of the

Correspondence: Scott Parker, Simmons & Simmons, CityPoint, One Ropemaker Street, London EC2Y 9SS UK
Tel: +44 (0)20 7628 2020
Fax: +44 (0)20 7628 2070
E-mail: Scott.Parker@simmons-simmons.com
Web: www.simmons-simmons.com

innovator pharmaceutical industry have argued that 'incremental modification' is simply a low-risk means of cashing in on the success of established products which brings little or no health benefit at the expense of fragmenting the market and/or delaying generic entry, diminishing the rewards rightly due in respect of the 'breakthrough' product and imposing strain on R&D resources that would be better applied elsewhere. In reply those defending the industry have argued that what is complained of is in reality a consequence of parallel development programmes and improvement that results in greater therapeutic choice for patients, safer and more effective medicines and a valuable source of competition both during and after the patent life of the 'breakthrough' product that exerts a beneficial influence on drug pricing. Related issues include the cost of pharmaceutical research and development and the shortening of the commercially most valuable period of patent protection (ie the patent life remaining post product launch) caused by the delay between filing for a patent on a new compound and getting that product to market. It is not the purpose of this paper to advance this debate but rather to step back and consider the legal issues on which the debate is (or should be) founded.

TO WHAT EXTENT ARE THE ALLEGATIONS OF 'EVERGREENING' OF GENERAL APPLICABILITY?

A review of the literature in this field reveals that many of the criticisms are focussed primarily upon the interaction between the patent and regulatory systems in the United States and Canada. Concern has been expressed that in the US innovator drug companies have been able to use provisions of the Hatch–Waxman Amendments to the Federal Food, Drug and Cosmetics Act to delay or deter the launch of generic competitor products. In particular, instances have been complained of where the innovator pharmaceutical company has allegedly used the listing of additional patents in the 'Orange Book' to try to benefit from more than one 30-month period of stay of the FDA's approval of the abbreviated new drug application (ANDA) and in this way extend its period of protection from generic competition. Similar complaints have been made in Canada where the regulatory environment for pharmaceuticals is (in this respect at least) similar. It is worth noting, however, that subsequent to recommendations by the Federal Trade Commission (FTC) amendments have been made to the US law that are designed to correct these alleged abuses of the regime. The Government of Canada has also proposed amendments to accelerate the market entry of generic versions of patented pharmaceuticals.

It may then be that certain of the specific allegations levelled against the innovator pharmaceutical companies in the US and Canada have already been addressed by legislative action. Nevertheless, a number of more general and ill-defined criticisms have also been raised which need to be considered in the context of other countries (even those such as the United Kingdom) which do not have an equivalent of the 'Orange Book' system.

WHAT ARE THE CRITICISMS OF SO-CALLED 'MINOR VARIATIONS'?

The more general criticisms within the 'evergreening' umbrella are summed up by the European Generic Medicines Association (EGA) as 'repeatedly creating line extensions and so-called "next generation" drugs, incorporating minor, normally therapeutically insignificant, variations to a product and patenting it as a new medication'.[1] Examples of the types of 'minor variations' that are being referred to by the EGA are set out by the National Institute of Health Care Management (NIHCM) in its 2002 report, 'Changing Patterns of Pharmaceutical Innovation', which refers to 'minor features such as inert ingredients and the form, colour and scoring of tablets'.[2] Other modifications that are sometimes included in the list of 'minor variations' that are allegedly used to extend a product's patent life in a way that is seen as harmful to the market include the following: dosage forms, delivery systems, combination

products, uses for new indications, specific enantiomers, salts, esters and crystalline forms and means of manufacture.

The purpose of this paper is not to evaluate whether or not these 'minor variations' may be of significant therapeutic value. While it is certainly the case that some improvements are of greater therapeutic benefit than others there are many examples of very significant benefits to patients arising from improvements that could be said to fall within such a list of 'minor variations'. This is well documented elsewhere.[3] Accordingly, where criticisms are to be made they should be levelled against specific drugs or patents and not against particular classes of innovation.

Our aim is to consider whether from a legal perspective the patenting strategy that is complained of by the generics industry really is capable of delaying or preventing the entry of a generic product onto the market.

THE LEGAL BACKGROUND

The patent system provides an incentive for companies to incur the cost and risk of research by providing the time-limited exclusive right to commercialise a patented product. At the heart of the patent system in the UK (and all other fully TRIPs compliant countries) is the requirement that to qualify for the monopoly right that the patent confers (20 years from the date of filing the patent application) the invention covered by the patent must be novel, non-obvious (ie it involves an inventive step) and capable of industrial application ('utility' or 'usefulness' in the US).

The novelty and inventiveness of the patent is evaluated against the 'state of the art', which consists in general of every item of information which has ever been made available to the public by any kind of publication, or by use, anywhere in the world, at any point in time before the first filing date of the patent. It is a basic principle of patent law that once details of a product have entered the public domain (by being published anywhere without patent protection, or when any patents for the product or proposal expire or lapse), then everyone has freedom to use that information and any obvious developments of it.

So before assuming that any new development relating to a known compound can be patented, we have to ask:

1. Is this new? Any previous publication or use, no matter how obscure, of the same invention destroys novelty and prevents a patent being issued or, if issued in ignorance of such a publication, this will subsequently cause the patent to be declared invalid if sought to be enforced.
2. Is there an inventive step? A patent cannot be granted for anything which is simply an obvious development or variant on any individual piece of information which is part of the state of the art. It is no answer that the piece of information in question may never have come to the attention of the fictitious 'person skilled in the art' who is central to any determination of 'obviousness'.
3. Is there a proposed industrial application for the invention (in the broad sense of having some useful purpose)? The invention does not have to demonstrate an improvement on what is already known, but it cannot be speculative. It must have a use. For example, a DNA sequence for a recombinant gene fragment with a well-defined function is a patentable invention whereas a DNA sequence alone without any indication of function or of its useful attributes is not.
4. Does the patent describe how to put the invention into effect? The patent must be 'enabling'; it must add to public knowledge, and contribute in its own right to the state of the art. In this way each new patent moves the frontier of the state of the art forward and makes it more difficult to find improvements which are neither old nor obvious. This disclosure enables third parties to implement the invention once the patent has expired and, is the consideration (in the legal sense) for the monopoly right granted by a patent.

HOW THE PATENT SYSTEM DEALS WITH 'EVERGREENING'

The criteria of patentability set out above apply equally to all inventions from the most basic mechanical patent to the most complex microelectronic or biotechnological invention. Similarly patent law does not distinguish between the invention of a wholly new product and inventions relating to improvements upon an existing product. The same criteria for patentability apply.

'Double patenting' is prohibited. That is to say the same invention cannot be covered by more than one patent. Thus for an improvement upon an existing pharmaceutical product to be patentable in its own right it will need to satisfy the criteria of novelty and non-obviousness taking into account the earlier product and all that is known about it in the public domain at the time that the second patent is applied for. If a patent is granted in respect of this improvement it will only cover the improvement to which it relates and will not extend to the originator product. That is to say a patent for a new product in a class will always be broader than any subsequent patent covering an improvement, modification or derivative of that product and so the exclusivity granted is in broad terms commensurate with the scope of the scientific advance that it reflects.

An important corollary to the prohibition on 'double patenting' is that a patent covering an improved version of a pharmaceutical (or any other) product does not preclude a generic company from copying all forms of the originator product once the patents protecting these forms have expired. For example, if a company selling a patented pharmaceutical reformulates that product as a syrup for paediatric administration and then patents the new formulation, generic competition to the original adult formulation will be possible once the patents covering it expire or are invalidated. The existence of the patent on the paediatric formulation will not delay or prevent generic competition on the original formulation. The innovator company will, however, continue to have the exclusive right to sell the paediatric formulation for the remainder of the life of the patent covering this specific improvement.

If in the above example the improvement made is not a paediatric formulation but a slow release formulation that allows once daily dosing and so improves patient compliance as a result of increased convenience, doctors and patients will have a choice between generic versions of the original formulation or the new once-daily product once any patent on the original formulation expires. The patents on the slow release formulation will not delay or prevent marketing of the original formulation. The market will then decide whether the benefits offered by the improved formulation make it worth paying for in the face of cheaper versions of the original product. The answer to this question will inevitably vary from market to market and between different patient populations. Either way the patient would appear to benefit from the increased choice available.

A simple and further example of this is ibuprofen. The supermarket shelf carries premium-priced ibuprofen formulations which typically are quicker acting or easier to take than the traditional tablet. These formulations may be patent protected. Customers can, however, decide for themselves whether the added benefit is worth the extra cost. The patents do not prevent anybody from buying the ordinary, cheapest kind of tablet.

Reference to patents covering the colour and scoring of tablets has been made in several articles criticising the pharmaceutical industry (without the specific patents that are complained of being identified).[4] It is informative to consider how the patent system would apply to such 'developments'. To the best of the authors' knowledge no patents have ever been granted for the colour of pharmaceutical products. In fact, since UK patent law (and most others) expressly excludes the patenting of 'aesthetic creations' the colour of a pharmaceutical product could only ever be patentable if either: (a) it could be established that the colour itself produces a technical effect, such as a therapeutic benefit caused by increased compliance, that is novel and not obvious; or (b) that the means of obtaining that colour, the manufacturing process of colouring the tablet, is itself novel

and not obvious. It goes without saying that for a 'pink pill' patent application the technical effect, novelty and inventiveness would be scrutinised carefully. Nevertheless, the application would be looked at on its own facts and applying the patentability criteria described above. Similarly, as regards the scoring of tablets, the same standard of patentability and scrutiny must be satisfied. It would need to be established that tablets had never been scored in this way before and that to do so was not an obvious departure from what has gone before. Without further investigation it should not be assumed that such an invention would be of no value to patients (eg it could be that compliance among children would be improved if the tablet is more cleanly cut as a result of the means of scoring employed). There are plenty of examples of developments (reformulations, new salts, combinations and the like) that have real therapeutic benefit but which at first blush may seem trivial.

Again, the more minor that a variation is (eg a pink tablet or means of scoring the tablet) the more narrow the relevant patent protection will be and the easier it should be for a competitor to design around the patent without needing to seek to invalidate it. For example, if a patent is (or has been) granted that covers a particular colour of tablet or a particular means of scoring such tablet then such a patent would not stop a competitor from marketing (respectively) a different colour tablet or a tablet that is not scored or that is scored in a different way.

In summary, therefore, the patent system is inherently adapted to reflect how much innovation in fact takes place (by way of improvements to existing technology) and to prevent 'evergreening'. It allows the use of 'old' technology while protecting (and thus providing incentives for) improvements to that technology.

Another factor to be taken into account in any debate on the patenting of 'minor variations' is that it is not only the company that owns the patents covering the originator product that can patent improvements thereto. Other companies (including generics) can (and do) do this, with the consequence that there may be a number of companies having similar products (some of which may for a variety of reasons be better suited to particular patients) and healthy competition in the marketplace.

'STRATEGIC PATENTING'

A related charge that is sometimes made against innovator companies is that they file numerous patents on multiple attributes of a single product so as to create a 'patent thicket' that so complicates third-party research that it strangles innovation, or that they are guilty of what is sometimes referred to as 'strategic patenting'.[5] Implicit in these charges is that the only reason for filing these patents is maintenance of market share for as long as possible after the expiry of the patents covering the originator product itself. This is a serious charge that deserves to be looked at in more detail.

Of course, pharmaceutical and biotechnology companies (like companies in all other R&D-based industries) have patenting strategies. In no other industry is there any suggestion that companies should restrict themselves to patenting inventions that meet some higher standard over and above the basic criteria for patentability or that companies should not seek protection for certain types of technological advance or that exceeding a certain number of patents in a technical area is *per se* reprehensible. When one considers that intellectual property rights are the life-blood that propels pharmaceutical advances in the private sector (and to an increasing extent in the public sector as well) and takes into account the sums that are typically spent on a new product during the 10–15-year-period from discovery through pre-clinical and clinical trials to regulatory approval and market launch, any company that did not do all that it could to protect its inventions would be acting negligently towards its shareholders. On the subject of patenting strategies in the pharmaceutical industry the UK Patents Court judge Mr Justice Jacob (now Lord Justice Jacob) said in the case of *Synthon v SmithKline Beecham* 'I ask myself whether SB have done anything blameworthy…and I cannot see that they have. On the contrary, so far as I can see, they have employed competent and careful patent

agents to obtain for them the best patent position which they think they can get. It may be good, it may be bad, but they are doing their job and I see no criticism whatever in the conduct of SB'.[6]

If one accepts that the nature of pharmaceutical and biotechnological innovation (as with other R&D based industries) is most often incremental and cumulative then it follows that the patent system should reflect this reality. This is indeed the case. As we have seen above, the patent system does not distinguish between 'break-throughs' and 'incremental improvements' in terms of the patentability requirements that apply. At the same time a greater reward (a broader patent) is granted in respect of the ground breaking research than for inventions directed at solving further technical hurdles and optimisation of the initial invention.

In the experience of the authors most of the patents that have been challenged by generic companies wishing to enter the market were applied for during the development of the originator product rather than once it has been established as a commercial success. This reflects the organic process of drug discovery and development and the time lag between drug discovery development, clinical testing and regulatory approval (ie that inventions are made in overcoming the various technical challenges faced during drug development). Nevertheless, some innovations are made at a later stage. For example, it may be that it is only after the product has been prescribed to a population of patients post-launch that it will become evident that further improvements need to be made to improve efficacy, deal with a compliance (or other) problem or expand the target patient population or disease indications. Such improvements may stem from greater experience of the product, problems unexpectedly encountered in particular patient populations or other advances made in the field. Given that the purpose of the patent system is to encourage innovation and (in the pharmaceutical sector) to lead to better medicines, it would be strange indeed if this incentive was removed or diminished once the first product of a particular type has been launched.

'WEAK' PATENTS – WHAT ARE THEY AND HOW DO THEY COME TO BE?

In a 2004 paper entitled 'Ownership of knowledge – the role of patents in pharmaceutical R&D' two sources of the 'weak' patents that are complained of were identified, namely 'lax rules on patentability' and 'shortcomings in the patent examination process'.[7] We shall consider these in turn.

Lax rules on patentability

As has been indicated above, the rules on patentability in most advanced countries are designed to apply the same threshold. It is not the role of the patent system to manipulate the market by offering increased incentives for research in a particular field or of a particular type. To the extent that this is necessary there are many better ways to achieve this (eg tax incentives, legislation such as that supporting 'orphan drug' research and public (and shareholder) pressure). Accordingly, the distinction made by the FDA between the 'most innovative' types of new drugs, those that provide 'moderate innovation' and 'modest innovation' is irrelevant when assessing patentability. There are no gradations of novelty or non-obviousness.

Importantly, the analysis of patentability must be made without the benefit of hindsight. This requires that the patent office or court tasked with determining validity (and the scientific experts assisting the court in this analysis) may be required to look back almost 20 years to consider the 'state of the art' at the time that the patent was filed. This is difficult to do, particularly in a fast moving field such as molecular biology or biotechnology where the use of what is today taught to undergraduates as a routine technique would 20 years ago have been cutting-edge research. Inevitably a failure to get inside the mindset of the 'person skilled in the art' at the time of the filing (the correct test for inventiveness) and to ignore all that they have learnt since then, causes many more patents to be seen as 'weak' than is actually the case. An example of the way in which the threshold of what is patentable

changes over time as technical advances are made and the 'state of the art' develops is in the area of chiral chemistry. In the 1980s the synthesis (or separation) of a single enantiomer from a racemic mixture was often difficult to achieve. If the pure enantiomer could be obtained and shown to have improved efficacy or reduced toxicity compared with the racemic mixture of the two enantiomeric forms, then this would most likely have been an invention deserving of patent protection. Indeed, a number of such patents have been granted (some of which relate to successful products). Nowadays, however, (and always depending on the facts) it may be more routine for a pharmaceutical company to look at the properties of particular enantiomers. Accordingly, it may be expected that it would now be more difficult to obtain a patent covering the use of an enantiomer of an already known chiral molecule.

It is of fundamental importance that the measure of the degree of inventiveness required for an invention to be patentable is set at the right level. Notwithstanding international conventions such as TRIPs and the European Patent Convention the attitude of patent examiners and the courts varies from country to country (as can be seen by the fact that it sometimes happens that a patent will be invalidated in one country, only for an identical patent to be upheld in the courts of another country) and so this is a question that needs to be addressed on a country-by-country basis. This paper is clearly not the place for such a review. Suffice to say that in the UK the perception is that the patents judges are not hesitant to revoke invalid patents and that it should be expected that short shrift will be given to patentees' attempts to claim too broadly. The standard of inventive step that a patent must satisfy in order for it to be upheld by the UK court is widely seen as being a tougher test than in many other jurisdictions. Accordingly, in the UK the criticism is more often levied (and not just by innovator pharmaceutical companies) that the standard of patentability applied by the courts is now set too high.

Shortcomings in the patent examination process

So how can the situation exist where it is not uncommon for a patent to be granted following objective examination by a patent office only to be subsequently invalidated by a court?

The number of patent applications being filed is increasing in most patent offices around the world. The effect of this is to increase the pressure on patent examiners who in the course of a single day may be required to review a number of patent applications in detail, review the prior art and evaluate patentability. It is also the case that the majority of patent applications most probably reside in the grey area between applications which on a preliminary review may be seen to be clearly weak and which should be rejected and those that clearly satisfy the requirements of patentability. In the circumstances the results of the UK and European offices are generally quite satisfactory and many applications are weeded out at this stage. Unlike in the US there are no presumptions made in the European examination process that favour the issuance of a patent. No matter how well trained and specialised the examiners and how thorough the searching it is inevitable that some patents will be granted which should not have been.

It is important to keep in mind that the overwhelming majority of the patents reviewed by a patent examiner will have no economic value and that there is no way of the examiner knowing which are the commercially important ones. In contrast, the patents litigated in the pharmaceutical industry typically relate to products that are of great commercial value. It is hardly surprising that with significant economic benefit riding on the outcome of litigation and far greater time and resources available, a generic company seeking to invalidate a granted patent may identify new prior art that was not identified in the examination process that calls into question the validity of the patent.

In Europe generic companies can avail themselves of the opposition procedure that exists for the patents in all of the designated European countries to be invalidated centrally at the European Patent Office. This procedure

allows interested parties a nine-month period from grant of the patent within which to apply to revoke a patent that they believe should not have been granted. Not only is this system a more cost-effective means of challenging validity but it is also a valuable check on the examination process in which competitor companies, who will be far better placed to identify 'trivial' patents that they believe may unfairly affect the market and to apply the resources needed to invalidate them, have the chance to contribute. It seems that there is now widespread support for such a post-grant opposition procedure to be introduced into the US granting process.[8]

WHAT IS THE EXTENT OF THE ALLEGED DELAY SUFFERED BY THE GENERIC INDUSTRY?

We accept that no matter how much investment is made in improving the world's patent offices some patents will be granted which should not have been. We must therefore consider the impact that such patents may have on the industry in terms of both the delay and expense of bringing legal proceedings to revoke these patents.

Any analysis which concludes that a truly 'weak' patent will deter a generic company from entering a market where, absent that patent, a good product opportunity exists is flawed and underestimates the sophisticated nature of today's generic industry. Such companies now employ first class patent attorneys, lawyers and patent researchers in-house. Even where this is not so the cost of instructing external lawyers to provide a validity opinion is negligible in comparison to the potential gains to be made. Such companies will also prepare carefully for their product launch (including planning for the revocation of any blocking patents) in sufficient time that the generic product can be launched promptly after the expiration of the 'primary' patent(s).

Delay in market entry therefore is more likely to be caused, it is submitted, by litigation procedures in certain countries which frustrate the attempts of generic companies to clear blocking patents out of the way.

In the UK the legal system is in fact helpful to companies seeking to invalidate a patent in a cost-effective and timely manner for a number of reasons: (i) unlike in the US there is no presumption that an issued patent is valid and no requirement that invalidity must be established by 'clear and convincing evidence'; (ii) patent cases in the UK are heard by a highly specialised judge (no jury trials) who may be guided on technical issues by independent technical experts; (iii) as mentioned above the patents judges in the UK are not hesitant to invalidate patents that they perceive to be unworthy of protection; and (iv) following the cases of *SmithKline Beecham v Generics UK* and *SmithKline Beecham v Apotex Europe*[9] the UK Patent Court has made it clear that the onus is now on the generic competitor to 'clear the path' of any existing patents before it begins its commercial activities. The effect of these decisions is that generic companies now know they must launch revocation actions in sufficient time to allow for revocation actions (and typically a subsequent appeal) prior to launch and therefore plan for this.

Compared with many other jurisdictions, patent litigation in the UK is also quick. Since the introduction of the Civil Procedure Rules in 1999 pressure has been applied to increase the speed of litigation and decrease its cost. It is now the case that most patent cases reach trial within one year of proceedings being launched and a Court of Appeal hearing will typically follow within about six months of the first instance judgment. In addition, procedures for 'speedy trial' and the following of a 'streamlined procedure' now exist and in appropriate cases a revocation action may be brought to court in as little as four months after proceedings are launched. Indeed, in *Mayne Pharma v Pharmacia Italia* the judgment of the Court of Appeal was delivered within nine months of proceedings being started.[10] Also the winning party will typically be awarded around 70 per cent of its legal costs by the losing party thereby significantly reducing the cost of entry to a successful generic company.

The authors recognise that in other countries the procedure for revoking a patent may be slower and more expensive than in

the UK, for example a 2002 FTC study states that in the US the average time between filing a patent infringement action and a court of appeal decision is almost 38 months. Problems such as this are, however, generally inherent in the judicial systems of the countries in question and are not a result of the patent system *per se* or any manipulation of the patent system or court procedure by patentees.

In conclusion, the allegation that pharmaceutical companies have been able to delay substantially the entry of generic competition by 'evergreening' many of their patents simply does not reflect the reality and mischaracterises how the patent system operates in the context of technological innovation. A patent over an improvement does not restrict a generic company from launching a competitor of the originator product and, in the UK at least, the procedure and attitude of the court is conducive to the speedy and cost-effective challenge of 'weak' patents.

References and Notes

1. See the European Generic Medicines Association website at http://www.egagenerics.com/gen-evergrn.htm.
2. Changing patterns of Pharmaceutical Innovation – A research report by the National Institute for Health Care Management Research and Educational Foundation – May 2002.
3. The importance of incremental innovation for development. A submission to the World Health Organisation's Commission on Intellectual Property Rights, Innovation and Public Health by the International Chamber of Commerce's Commission on Intellectual Property, 2005.
4. Indeed, in 2002 President Bush referred to '…patents based on minor features such as the colour of the pill bottle or a specific combination of ingredients unrelated to the drug's effectiveness…' in announcing reforms aimed at combating alleged abuses that have kept generics off the US market.
5. To promote innovation: the proper balance of competition and patent law and policy. Federal Trade Commission Report 2003, http://www.ftc.gov.
6. *Synthon BV v SmithKline Beecham,* PLC 14th February, 2003 Ch D (Patents Ct) (Jacob J) LTL 25/2/2003.
7. Ownership of Knowledge – the role of patents in pharmaceutical R&D. Correa. Bulletin of the World Health Organisation October 2004, 82(10), 784–790.
8. Drafts of a patent reform bill that provides for the introduction of a post-grant opposition procedure and a switch from the present 'first to invent' patent system to one founded on the 'first inventor to file' are presently under review by the US legislature. If enacted in a form similar to the discussion draft this would go a long way towards harmonising patent law between the US and Europe.
9. *SmithKline Beecham and others v Apotex Europe and Others* 2002 EWHC 2556 (Pat). *SmithKline Beecham v Generics UK* 2002, IPD January 2005.
10. *Mayne Pharma and another v Pharmacia Italia* 2005. LTL 17/2/2005: 2005 28(3) IPD1.