# IPO COMMITTEE NEWSLETTER

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Written by Members of the IPO Patent Law and Practice (International) Committee

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# WILL BRAZIL CROSS-RETALIATE AGAINST THE U.S. BY SUSPENDING OR LIMITING INTELLECTUAL PROPERTY RIGHTS AFTER THE CONCLUSION OF THE "COTTON CASE" AT THE WTO?


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Given the well deserved wide public coverage received by this dispute, on this brief we want to mainly focus on some of the particular potential measures that Brazil may take against intellectual property rights (IPRs) by U.S. citizen and companies, which is just one of the many issues at stake.

**1. Latest development on the case**

As informed on the IPO Daily News™ on April 7, 2010; the governments of Brazil and the U.S. reached *a preliminary agreement* on April 6 that avoided (or, properly speaking, delayed[1]) the entrance in force of the retaliatory (consisting on u$s591 million in the form of higher tariffs to be applied on a broad list of US goods imported into Brazil) and cross-retaliatory (up to u$s 239 million in the form of restrictions, suspensions and others described below, of IPRs owned by U.S. nationals) measures[2].

Just when the Brazilian Government was going to start implementing those measures, a provisional agreement was reached and now, according to unofficial sources, there is a period until April 21 for the U.S. to show demonstrable efforts in implementing its short term commitments until broader changes related to official programs for subsidies and credits to the cotton industry come in place, likely at the next Farm Bill that will be entering the Congress soon.

**2. Brief history recount of the facts that led to this provisional agreement.**

Those sanctions were the result of the award granted by a WTO arbitrator on August 31, 2009, which concluded the corresponding WTO proceedings known as "the cotton cases" started in 2002. The award confirmed that the Brazilian Government could impose certain retaliatory and cross-retaliatory measures for a value of 830 million[3] given that the U.S. subsidies on cotton violated existing international regulations.

That award was internalized by the Brazilian President through the enactment of Provisional Measure No. 482, which was published on February, 18 2010[4] and established the general mechanisms to impose the cross-retaliatory measures tackling IPRs.[5]

Article 3 set forth the following measures: I) suspensions of IPRs; II) limitations to IPRs); III) change of measures for the implementation of standards of protection of IPRs and IV) for obtaining and maintaining IPRs; V) temporarily blocking the remittance of royalties or compensation on the exercise of IPRs; VI) application of commercial rights on the remuneration of the holder of IPRs. Article 6 established that those measures could be taken individually or cumulatively, as approved by the Resolution of the Council of Minister of the Board of Foreign Trade (CAMEX) and

[1] The particular retaliatory measures were schedule to enter in force on April 7, 2010.

[2] The main difference between retaliation and cross-retaliation under the WTO provisions is that the latter are related to sectors regulated by the WTO different from the one violated by the offending country. However, cross-retaliation has no punitive nature but compensatory.

[3] Brazil was initially seeking to impose measures for u$s 4 billion.

[4] Its "Unofficial" translation is available at https://www.uschamber.com/assets/busbc/executive_order_english.pdf

[5] Article 4 described the IPRs reached by the Provisional Measure such as a) copyrights and related rights (including the protection of computer programs); b) trademarks; c) geographical indications; d) industrial designs; e) patents (that included the protection of plant varieties or cultivars); f) topographies of integrated circuits; g) protection of confidential information and protection of undisclosed information.

described certain procedures (including some tax and trade related) for doing so. Provisional Measure 482 set forth that before implementing such measures it was required the participation of CAMEX and the holding of public hearings.

Then, COMEX issued Resolution No. 15 on Mach 5, 2010 describing the particulars of such cross-retaliatory measures and, on March 12, issued Resolution No. 16 establishing that the implementation of those measures had to be subject of public consultation but comments could be submitted within 20 days from the publication of the Resolution.

Annex II of Resolution No. 16 detailed cross-retaliatory measures such as compulsory licenses without payment of royalties (as it is mandated by TRIPs); particular application of sanitary regulations (for U.S. pharmaceutical, agricultural and agro-biotechnology products) including non legal protection of undisclosed test data protection; increase of official fees; and other potential measures. The main U.S. industries and sectors that would be affected by these cross-retaliatory measures are music and movies, pharmaceutical and chemical and biotechnology.

**3. How this preliminary agreement between the governments may affect other international IP matters?**

So far the threat of using cross-retaliation on IPRs in this case has proven to go beyond the limits set by the prior similar victories at the WTO of Ecuador over the European Union (no sanction were implemented by that country) and of Antigua over the U.S. where the same happened.

Let us recall that since the entrance in force of TRIPs, there have been some authors within the IP International Community advocating that developing countries should use strategies like this one implemented by Brazil against IPRs owned by "nationals of developed countries". According the some observers, after this case the number of such advocates and their followers are very likely to increase.

In our view, however, using diplomacy seems to better than resorting to WTO cross-retaliation measures affecting IPRs, which are a very delicate matter with multiple dimensions in terms of geography (local measures have international effects); timing (measures that may be seem as beneficial in the short term may result in greater harm in the long term); and others.

Focusing on this case, cross-retaliation over IPRs owned by US nationals may spur unforeseeable negative effects to be borne not only by the title holders (who may have nothing to do with the principal dispute) but also by individuals and companies in Brazil. Such could be the case of Brazilian inventors and companies (private or public) who are interested in partnering with U.S. companies and individuals to invest on R&D, form joint ventures to develop new products and/or to commercialize and distribute existing products in new markets. If cross-retaliation were to be implemented, not only such existing projects might be suspended or shut down but also would most likely take years to restore the trust on the observance to the rule of law in relation to IPRs given the legal uncertainty created.

Overall, the use of cross-retaliation measures over IPRs as a general strategy should be seriously analyzed taking into account its administrative costs together with its net economic value for the offending country; as it is very likely to harm producers of intangible goods; consumers in general; and in some extent, even the government; of the offended country.

One remote positive consequence of this dispute may be to encourage moving forward with the conclusion of the Doha Round (sponsored by the WTO) that serves as the umbrella or focal point for most of the issues discussed in this dispute that affect multiple industries affected directly or indirectly.

## IP LAW IN MODERN DAY CHINA: A LOOK AT THE EVOLVING PATENT LANDSCAPE


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China's intellectual property system is less than thirty years old. While the development of the system has not always been smooth, its progress has been unparalleled. China's patent office (SIPO) and trademark office (CTMO) are now the largest in the world, the country's intellectual property legislation is modern and in line with world standards, and its record of spotty enforcement is steadily improving.

What seems to have made the difference in China's approach to intellectual property is an attitude shift within the Chinese government. China has now recognized the role that intellectual property rights can play in the continued development of the country's socialist market economy, and in recent months the government has adopted or announced its intention to adopt a number of significant legislative acts and judicial decisions that strengthen the protection afforded intellectual property. Although the stated objective of a strengthened Chinese intellectual property rights system is to foster domestic inventiveness and build an innovation-oriented China, the systematic improvements also provide improved protection for foreign companies.

*Patents*

On October 1, 2009, the Third Amendment to the Chinese Patent Law took effect, followed on February 1, 2010, with the entry into force of detailed Implementing Regulations. Unlike the previous amendments to the Chinese law that were arguably products of external pressure from the United States, other industrialized countries, and the World Trade Organization, the Third Amendment appears motivated solely by internal forces – no foreign request or international treaty prompted the amendment – making it all the more significant.

The Third Amendment has changed patent law in China considerably. Some of the more notable modifications include:

**Absolute Novelty Requirement**

While all patent laws require novelty as a condition for patentability, the definition of novelty varies from country to country. China used to apply a local novelty standard for prior use of the invention, but the new law adopts absolute novelty, a standard that is even more rigorous than that found in the U.S. Patent Act. Under the new law in China, if an invention was known to the public *in any country* in the world prior to the filing of a patent application, the invention is not novel.

**Statutory Damages**

The former law permitted only RMB 10,000 (about $1,465) as statutory damages in compensation for patent infringement. While damages under the new amendment are still relatively low, the statutory amount has been increased to RMB 1,000,000 (about $146,533), and compensation is now also available for reasonable expenses incurred by a patent owner.

**Co-ownership Issues**

The new amendment filled a gap in the Chinese law, which previously lacked adequate regulation of co-ownership. Under the new amendment, and similar to U.S. law, where there is no agreement between patent co-owners, each may practice the patent or grant non-exclusive licenses with all license fees shared among the co-owners.


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**Foreign Patent Applications**

Previously, foreign applicants wishing to apply for or maintain a patent in China had to work with an agent from a group of State Council-designated agencies. The Amendment now allows all patent agents in China to handle foreign applications, thus opening up the pool from which applicants may choose, but perhaps more importantly, focusing national attention on the need to improve patent agent training and qualifications.

These developments are not only reflective of a government that has begun to emphasize intellectual property, they are also motivated by the growth and increased experience of Chinese companies. For example, in 2009, SIPO received over 976,000 patent applications. More than 877,000, or nearly 90%, were from Chinese applicants. Those numbers have skyrocketed up from 573,000 and 470,000 applications, respectively, in 2006 (82%) and 694,000 and 586,000, respectively, in 2007 (84%). Moreover, Chinese applicants are now the fifth most frequent filers of PCT (international) applications, following only behind applicants from the U.S., Japan, Germany, and Korea, and it is expected that Chinese applicants will overtake those from Korea by the end of 2010.

What is more, Chinese companies have been increasingly willing to bring actions to protect their patent rights as well as to defend themselves more assertively in infringement cases. One result is that some Chinese courts have begun to grant damages for patent infringement that exceed the statutory amount. Examples include an award of $48.5 million – the largest ever – issued by the Wenzhou Intermediate People's Court in *Chint v. Schneider Electric* (the case ultimately settled for $23 million), a more recent award of $7.4 million by the Hangzhou Intermediate People's Court in a case brought by Holley Communications against Samsung Electronics, and a lawsuit recently filed by Yi Du & Masep Medical Technology Division against Concord Medical Services Holding Ltd (two Chinese companies) in the Shenzhen City Intermediate People's Court seeking damages of $25.7 million. A Judicial Interpretation by the Chinese Supreme People's Court concerning the trial of patent infringement cases, which became effective on January 1, 2010, should help streamline and foster consistency in patent litigation throughout the country, in particular, concerning the calculation of damages.

Chinese companies also seem to be engaging more assertively in litigation in the U.S. In the past few years, Chinese company Protecht Group, Inc. successfully defended itself against a claim of patent infringement in U.S. District Court, computer manufacturer Lenovo Ltd. sued in the U.S. based on patents it acquired from its purchase of IBM's PC division, and flash-manufacturer Netac Technology Co. filed an action in Texas District Court against U.S. manufacturer PNY Technologies, just to name a few. These efforts, which are likely to grow and have an impact on government policy, suggest a growing awareness by Chinese companies of the value intellectual property brings to their businesses.

*Trademarks*

China's intellectual property coming of age is not limited to patent law. On the trademark front, the China State Council issued an Outline of the National Intellectual Property Strategy, which recognizes that trademarks are "a strategic resource in national development and a core element in international competitiveness, an important supporting force in building an innovative country, and a key to holding the initiative in development." China has since prepared a new revised Trademark Act, which is likely to be adopted within the next year or so. The proposed improvements should benefit U.S. applicants by, for example, increasing the scope of registrable marks to include color and non-visual marks, allowing multi-class applications, and increasing the amount of statutory damages and administrative fines. Furthermore, the Supreme People's Court of China has issued several opinions within the last year that guide courts on how to approach various trademark and unfair competition issues, including the

important issue of protection for well-known trademarks.

China has come a long way since it first embraced intellectual property protection. It is now a serious player on the world's intellectual property scene, and one that must be taken seriously in any company's determination of where to seek intellectual property protection. Put simply, China should no longer be ignored.

# IS EXPERIMENTAL USE AN EXCEPTION TO PATENT INFRINGEMENT IN AUSTRALIA OR NEW ZEALAND?


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Imagine you are a medical researcher and have identified a chemical compound that might be a promising drug. The compound itself isn't new, and the use and making of the compound itself are covered by the claims of a patent. Are you able to go ahead and experiment on the compound with a view to developing it as a drug? Or will you be liable for infringement of the patent?

This topic is an important one in Australia because under the current Patents Act 1990 and court precedent in Australia there is no general exception to infringement for activities that could be called "experimental uses" of an invention. A similar situation exists in New Zealand. Such uses could include determining how the invention works, evaluating the validity of the patent claims, or seeking an improvement to the invention. Recent reviews of the law have suggested that such an exception to infringement would be to the advantage of Australia and New Zealand's innovative capacity. Draft amendments to the Patents Acts in each country have been proposed and accepted in principle by the government. However, no statutory exception has yet been enacted. Today it is still the case that there is no broad exception for experimental use in either Australia or New Zealand. Limited exceptions to infringement are available for obtaining regulatory approval of pharmaceuticals, but only if any relevant patent is in an "extended term".

**Proposed Experimental Use Exception Not Yet Enacted**

The Advisory Council on Intellectual Property (ACIP), a board of expert advisors to the government on IP law issues, reviewed the legal and business issues surrounding the idea of a general and statutory experimental use exception in their report issued in 2005. ACIP recommended that the Patents Act be amended to include an experimental use exception. The language proposed by ACIP and accepted by the Australian government reads:

> The rights of a patentee are not infringed by acts done for experimental purposes relating to the subject matter of the invention that do not unreasonably conflict with the normal exploitation of a patent.
>
> Acts done for experimental purposes relating to the subject matter of the invention include: determining how the invention works; determining the scope of the invention; determining the validity of the claims; seeking an improvement to the invention.

The language is very similar to that of the European Patent Convention, and how the EPC provisions are interpreted may well influence how this proposed language is ultimately interpreted in Australia.

Despite this proposal, and although the Australian Government accepted in principle this proposed amendment, no amendment to the Patents Act has yet to be made as of the beginning of 2008.

The Australian Patent Office (IP Australia) has conducted two rounds of public consultation in 2009 and early 2010. These consultative

sessions involved written submissions and face to face discussions with interested parties. These submissions can be viewed at the IP Australia website (http://www.ipaustralia.gov.au/resources/news_new_archived_2009.shtml#77). At least one further round of public consultation is envisaged, and will likely involve an early draft of a Bill to introduce the legislation.

One result of the continuing discussion has been an apparent broadening of the scope of the exception from that proposed by the ACIP. The current proposal, taken from the most recent drafting instructions publicly available from IP Australia at least de-emphasize the limitation that any experimental use must "not unreasonably conflict with the normal exploitation of a patent." Indeed, the drafting instructions explicitly states that "[t]he existence of an ultimate commercial purpose for the study or experimentation should not preclude the application of the exemption." A similar approach is being adopted in New Zealand (see below).

Whatever language eventually emerges from this process, it is clear is that it will be some time yet before a statutory exception to infringement for experimental use goes before Parliament. The Government's legislative priorities at present are not focused on patent law. We might see legislation taken up within the next year or two.

**New Zealand Will Likely Introduce a Broader Experimental Use Exception**

New Zealand and Australian Patent Law often follow similar approaches to similar issues. The New Zealand Parliament has been digesting a new Patents Act introduced in 2008. The current version of the bill was recently reported out of Committee with several amendments. Notably, proposed Section 136 has been amended to expand the experimental use exception to infringement.

**136 No infringement for experimental use**

- (1) It is not an infringement of a patent for a person to do an act for experimental purposes relating to the subject matter of an invention.
- (2) In this section, **act for experimental purposes relating to the subject matter of an invention** includes an act for the purpose of—
    - (a) determining how the invention works:
    - (b) determining the scope of the invention:
    - (c) determining the validity of the claims:
    - (d) seeking an improvement of the invention (for example, determining new properties, or new uses, of the invention).

In this instance, at least in draft, the New Zealand legislation gives an apparently broader shelter to those who infringe than the Australian text proposed by ACIP quoted above. The New Zealand bill is also a distance from enactment, with further committee reports and debate in Parliament anticipated prior to the bill passing into law.

**Limited Exception for Uses Necessary for Regulatory Approval**

There is protection in both Australia and New Zealand from claims of infringement for some activities related to "spring boarding" of pharmaceuticals (and medical devices incorporating pharmaceuticals) that may need regulatory approval for marketing. This is a very limited exception to infringement, and is only available during any extended patent term.

Unlike other countries, such as Canada and New Zealand (discussed further, below), Australia does not have an express exemption from patent infringement when pharmaceutical substances are undergoing clinical trials for regulatory approval and when the patent is under its normal

term. However, if the patent has had its term extended, activities for regulatory approval during that extended term are exempt from infringement if done for regulatory approval. This exemption is created by Section 78 of the Australian Patents Act 1990 as amended. The regulatory approval sought need not be limited to Australia, but can be for any country.

Extensions of term are granted to patent claims that are directed to the pharmaceutically active ingredient (*i.e.* the compound *per se*) and for which initial regulatory approval took at least 5 years. The patent term extension is available for a period of up to 5 years (Sections 70 through 77 of the Patents Act). Most of the litigation concerning these sections involves controversies over whether an extension should be granted by the Commissioner of Patents and not infringement, *per se*.

Therefore, when considering if an AU patent claim to a pharmaceutical substance would be infringed by conducting a clinical trial, it is critical to determine if the patent is in its "normal" term or in an extended term.

**Obtaining Regulatory Approval in Australia**

Generally, all importation and manufacture of drugs for human use in Australia is governed by the Therapeutic Goods Administration (the TGA) under the Therapeutic Goods Act 1989. The TGA also regulates clinical trials. From a client's perspective, one need not necessarily first obtain registration as a therapeutic good with the TGA for the pharmaceutical formulation undergoing trial. However, in any event, the clinical trial must meet the relevant guidelines and be monitored by the appropriate authorities.

**New Zealand**

Although the patent laws of New Zealand and Australia are often similar in their operation and interpretation, the New Zealand law of exemptions from patent infringement for clinical trials is similar to that of Canada, rather than Australia. In New Zealand, activities reasonably related to obtaining regulatory approval (in any country) may be exempt from patent infringement regardless of any extension of term provisions. The new bill continues this exception to infringement in its Section 138.

**Conclusion**

Importantly, despite the continuing discussions and even though legislative action on this issue may occur in the near future, there is as yet no statutory exception to patent infringement for experimental uses in Australia, nor New Zealand.

# EUROPEAN PATENT OFFICE BOARD OF APPEAL ENDS USE OF SWISS-TYPE CLAIMS FOR PHARMACEUTICAL PATENTS


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The European Patent Office (EPO) Enlarged Board of Appeal (EBA) announced the end of Swiss-type claims in a decision published February 19, 2010. It held that "where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of a so called Swiss-type claim as instituted by decision G 5/83." EBA decision G 2/08, point 7.1.3.

Before discussing the Board's decision, it may be useful to review the two types of "use" claims that existed in the European Patent Office before the passage of EPC 2000 and up to the issuance of this opinion. The first and broadest type of use claim is the first medical use claim, which may be written as:

*Compound X for use as a medicament.*

The second and more narrow type of use claim is the Swiss-style claim, which may be written as:

*The use of compound X for the manufacture of a medicament for treating of disease Y.*

After considering the revisions to the European Patent Convention (EPC) in EPC 2000, the Board indicated that where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of a so called Swiss-type claim as instituted by decision G 5/83. Thus, the use of Swiss-style claims is to be forbidden in the future. Elsewhere in the opinion, the Board states that applicants must stop using Swiss-style claims no later than three months after the opinion is officially published in the Journal of the EPO, which has not happened yet.

Swiss-type claims were instituted by decision G 5/83 in 1984 and were intended to constitute a narrow exception to Article 54(5) EPC 1973, which only allowed patent protection for the first medical indication of a known composition in medicament form. Decision G 5/83 allowed for patent protection of subsequent medical indications of a known medicament. The EBA reasoned that the EP legislator did not intend to exclude subsequent medical indications from patent protection. The Swiss-type claim took the form: "Use of [a known substance or composition] for the manufacture of a medicament for use in [new therapeutic application]."

The EP legislator subsequently promulgated Article 54(5) EPC 2000, which completely closed the Article 54(5) EPC 1973 loophole that limited patent protection only to the first medical indication of a known composition in medicament form. Article 54(5) EPC 2000 was changed to allow for patent protection of subsequent medical indications of a known medicament. Since the new legal framework allows for such patent protection, the EBA has since determined that the G 5/83 Swiss-type claim was no longer needed. Decision G 2/08 allows for a simplified claim form: "[Known substance or composition] for use in [new therapeutic application]."

It is important to note that this change will not apply retroactively. It will only apply to applications having a priority date three months after the publication of decision G 2/08 in the *Official Journal of the European Patent Office*.

Moreover, decision G 2/08 generally considered the Swiss-type claim form and the new claim form that must be used as similar in scope. However, it is not clear how national courts will interpret the comparative scope of these claim forms.

## ELI LILLY v. HUMAN GENOME SCIENCES: A DIFFERENCE IN OPINION FROM THE EPO AND THE UK COURT OF APPEAL

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**Background**

In 1996 Human Genome Sciences (HGS) filed a patent application relating to Neutrokine-α gene and polypeptide sequences. The EPO granted a patent from this application in 2005, (EP0939804, the HGS patent).

The patent contained nucleotide and amino acid sequences for Neutrokine- α that had been predicted using computer techniques based on other members of the TNF super family of polypeptides. No experiments had been carried out in the laboratory to identify or to confirm any of these predictions, despite the patent containing a long list of uses for the novel protein, and activities that it may possess. All activities and uses were purely speculative and derived from activities and uses of homologous or other related polypeptides.

Following HGS's patent filing, third parties also independently discovered the polypeptide, through research in the laboratory over a period of time and at a large expense. It was one of these parties, Eli Lilly (Lilly), that challenged

the HGS patent at the EPO and also in the UK courts.

**EPO Opposition/Appeal**

In the EPO the patent was revoked by the Opposition Division, the patent proprietor subsequently appealed, and the Technical Board of Appeal (TBA) maintained the patent in amended form.

The opponent (Lilly) had argued that the patent did not meet the requirements of industrial applicability, since all of the information in the patent was speculative, (although it was later found to be correct). Lilly objected to the fact that a "boiler plate" list of activities and conditions had been included in the patent, and then as further data were generated, long after the initial filing date, the activities that were proven to be correct were "cherry picked" from the lengthy disclosure.

However the TBA took the view that the standard of proof had not been met by the opponent, i.e. a patent can only be found to be lacking in industrial applicability if serious doubts substantiated by verifiable facts are provided, which is in accordance with the EPO standard for assessing whether a patent is insufficient. The TBA considered that the allegations of lack of industrial applicability had not been substantiated in this way by the opponent.

Post-published data were also provided as evidence that there was indeed an industrial application for the novel polypeptide, which were taken into account by the TBA. Thus, the TBA found that the HGS patent met the required standards.

**UK Court of Appeal**

However, the UK Court of Appeal came to a different conclusion. Jacob LJ upheld the UK High Court's finding that the UK part of the HGS patent was invalid, since the claimed invention lacked industrial applicability.

Jacob LJ looked in detail at various case law from the EPO TBAs and found reasons not to take these into account, specifically that the TBAs differ fundamentally in their approach from the Courts with regard to the level of detail in which a case is assessed. He was careful not to criticize the TBAs of the EPO *per se*, but did point out that the TBAs do not work in the same way as the UK Courts, do not have access to the same information nor the methods of obtaining such information, for example, in terms of the cross examination of expert witnesses and discovery.

In order to assess whether the claimed invention met the requirements of industrial applicability, Jacob LJ stated that the use of the invention in the patent must be set out in such a way that is plausible and sufficiently precise, and that the patent in question did not meet the necessary levels of disclosure. The patent in question did not contain plausible uses since Jacob LJ considered that a research program would be necessary to work out which of the broad and contradictory range of listed uses were actually real.

He stated "*However clever or inventive you may have been in discovering a gene sequence, you cannot have a patent for it or for the protein for which it encodes if you do not disclose how it can be used"*

Jacob LJ also stated *"You cannot have a patent for an invention when only years later you or someone else finds out what it is for"* i.e. that post published data cannot be used as evidence to show that a speculative function was in fact found to be correct at a later date, in order to meet the requirement of industrial applicability. The patentee must have been in possession of the invention at the time that the patent was filed in order to show that the claimed invention does indeed have an industrial application. In fact, Jacob LJ stated that the need to rely on post published evidence is an indication that the information contained in the patent is not enough to ascertain the industrial applicability of the claimed invention.

Therefore, Jacob LJ stated that the patent, if held valid, would discourage research since the time, effort and money spent by *inter alia* Eli Lilly on something which HGS had not researched, would be rendered futile. Therefore, the monopoly provided by the patent should only be rewarded to those that have carried out sufficient research to actually have identified in real or at least in plausible terms the claimed invention.

**Summary**

Therefore, in view of this judgment it is clear that the patentee must provide clear, plausible information (ideally supported by data) within the application as filed (and thus in any resulting patent) that the claimed invention does indeed possess an industrial application in order to be found valid in at least the UK. This judgment could have far reaching consequences on biotech patent portfolios in the future, since many patent applications are filed once a sequence has been identified, before any research to identify its function has been carried out.