

A Prolific Year in Patenting — 2006 Patent Focus Report

By Joff Wild

Patent owners and their advisers had a number of major developments to take on board during 2005. While the focus for most of them continued to be on the jurisdictions covered by the Trilateral Authorities — the European Patent Office, the Japanese Patent Office and the US Patent and Trademark Office — both China and India grew ever more important. These two countries have offered major opportunities in R&D and manufacturing, both for domestic and foreign concerns, for some time. They are now establishing themselves as consumer markets of significance — hence their inclusion in this review of 2005.

CHINA

When China and intellectual property come up in the same conversation, the discussion is likely to centre on how difficult it is for companies to feel confident they can protect and enforce their rights in the country. However, the reality is that a more nuanced approach is probably required nowadays. While it remains the case that trademark and copyright owners are likely to come up against major counterfeiting and piracy problems at some stage, the picture is far less threatening for patent owners. For them, China may well pose challenges, but no more than those they face in many other parts of the world.

Report of the Office of the US Trade Representative

One indication of this is the most recent Section 301 Report of the Office of the US Trade Representative (USTR), published in April 2005, which identifies:

- countries which are deemed not to offer adequate protection to US IP owners
- the perceived shortcomings in their IP protection
- measures the US could take if improvements are not made.

In 2005, China was named a Priority Foreign Country — the highest category in terms of the environment for infringement of rights — and nine of the 65 pages of the Report were dedicated to the situation there. However, only two paragraphs within this nine page section dealt with patent-related matters, with the USTR stating that the narrow scope of patentable subject matter in China made patents for transgenic plants and animals virtually unobtainable; and that the lack of clarity in laws concerning generic drugs was contributing to the continued growth of counterfeit medicines. No other aspect of the Chinese patent regime was deemed to be worthy of comment.

However, that is not to say that patent owners could not experience major difficulties in China. In April 2005, Pfizer's appeal against the revocation of patents relating to Viagra was heard at the Beijing No.1 Intermediate People's Court. Pfizer launched this action after the

Patent Re-examination Board of the State Intellectual Property Office decided to invalidate the company's Chinese patent for the use of sildenafil, the active ingredient in Viagra, on the grounds of insufficient disclosure of the claimed invention. After hearing the case, the Court reserved judgment and its decision is expected in the early part of 2006. The outcome is eagerly awaited as the Viagra case has raised concerns about the patenting process in China — namely that it is not transparent or predictable. A decision by the Court to overturn the Patent Re-examination Board's findings will be greatly welcomed by patent applicants.

Increases in patent applications and disputes

Despite the concerns, the numbers of patent applications made in China continues to rise. During 2004 (the latest available figures) the State Intellectual Property Office received 130,000 applications for invention patents, half of which came from multinational companies based in the developed world. In certain sectors, overseas companies are by far the biggest applicants; for example, companies from developed countries made 93% of applications relating to electronic transmission, 91% in mobile telecommunications, 90% in audio and visual technologies, 85% in semiconductors, 69% in pharmaceuticals, and 60% in computing technologies. In fact, said Tian Lipu, Commissioner of the State Intellectual Property Office, when reporting these figures, just 0.03% of Chinese businesses own IP covering key technologies.

As the number of patent applications grows, so does the number of patent disputes. When it comes to enforcement, China operates a dual system, with both courts and patent administrative bodies able to hear cases. Despite some drawbacks — such as the non-availability of preliminary injunctive relief or damages — the latter continue to be the most favoured option, as they are relatively quick and uncomplicated. During 2004, local patent administration bodies accepted 1,455 cases involving patent disputes, and 1,215 of them were resolved.

Complying with international standards

Although China passed a TRIPs-compatible patent law in 2001, there are still some issues that have to be dealt with before the legislation can be said to comply with international standards in full. In the summer of 2005, therefore, a process started to consider amendments to the law. Changes being discussed include:

- introduction of a simpler patent application procedure
- implementation of the Patent Law Treaty
- changes to substantive law involving the criteria for novelty and inventive step, the scope of non-prejudicial disclosure, and patentable subject matter such as software-related inventions
- application of the doctrine of equivalents, prosecution history estoppel, indirect infringement, and the powers and duties of the patent administrative bureau

It is possible that new provisions designed to protect China's biological and genetic resources will also be added to the Patent Law, and Commissioner Tian has said he would be interested in seeing proposals relating to the establishment of specialist IP courts. Tian has stated that the revisions, which are expected to come into force in 2008, form an important part of the overall IP Strategy for China that the State Intellectual Property Office is currently developing.

EUROPEAN PATENT OFFICE

On July 1 2005, Latvia became the 31st member state of the European Patent Convention. This means that the European Patent Office (EPO) now has the authority to grant patents that are valid in countries with a combined population of more than 540 million people — a market greater than that of the US and Japan combined.

Set up by the contracting states to the European Patent Convention (EPC) back in the 1970s, the EPO made its first grants in 1980. Back then it handled approximately 10,000 applications a year; in 2004 (the latest available figures) the number came close to 180,000. As the number of applications has grown, so have pendency times. For direct filings to the Office these now stand at an average of nearly four years; for those applications that end up in opposition and appeals proceedings the wait can often be longer still.

Changes at the EPO

Alain Pompidou, the current EPO President, has overseen a number of projects at the Office designed to deal with the time it takes to get European patent protection. Following an extensive recruitment programme the number of examiners now exceeds 3,400, and more intensive training of examiners has also been implemented.

The EPO's organization was also restructured during 2005, including a reallocation of tasks and responsibilities between the various directorates-general. As a result of these and other initiatives, the search backlog has been reduced and the number of files in the examination phase has also decreased. Pendency times, too, have fallen but only to an average of 45 months, significantly more than the 36 month target given to the EPO at the Paris Intergovernmental Conference of EPC member states.

Extended European Search Report

The introduction of the Extended European Search Report (EESR) on July 1 2005 may help to speed the process of pendency reduction along. As a result of the EESR, all patent applications are subject to an enhanced service relating to the delivery of first opinions from examiners to applicants. These first opinions are to be provided by the examiner within an average of six months from the original submission of the application.

In the opinion, examiners outline their impressions of the strength of the application based on the claims and on the prior art. They can advise that in its current state the application does not look like a potential candidate for grant or, alternatively, that there appear to be few problems. Similarly, the examiner can also make suggestions as to how the application can be altered in order to stand a greater chance of making it through to grant. In providing this service at such an early stage in the application process, the aim is to allow the Office's customers to manage their patenting risks more effectively, and so gain greater value from their IP portfolios. Those applications that stand little chance of making it through to grant are more likely to be withdrawn, so relieving the EPO of unnecessary further work.

The perils of obtaining Europe-wide protection

While the EPO is able to put in place policies that have the potential to affect pendency times and patent quality, it is almost powerless in two other areas that continue to be major issues in Europe: the cost of patenting, and certainty.

The EPO, of course, does not issue patents that are enforceable across Europe. Instead, an applicant will nominate those countries in which it wants to be protected and, if the application gets the green light, the EPO will effectively grant national patent rights for each of those countries. The major problems with such a system are that to get Europe-wide coverage is significantly more expensive than it is to get protection for the whole of the US or Japan, while enforcement of rights is far less certain. Courts in, say, Germany and the UK will often reach completely different decisions in almost identical cases.

Back in the late 1990s, the Community patent was proposed as a centrally granted patent to cover the whole of the EU. It aimed to give patentees in Europe the certainty and cost savings they all say they want. Unfortunately, negotiations over its introduction continue to be hampered by controversies surrounding language and litigation, and the Community patent does not look like becoming a viable option in the near future. Likewise, the London Agreement on Translations, and the European Patent Litigation Agreement, remain stalled. However, here the news could be about to get better.

London Agreement on Translations

Under the London Agreement, countries that share an official language with the EPO, i.e. English, French and German, would not require translation of European patents in one of their official languages. Other countries would have to choose one of the official languages of the EPO as a "prescribed language", in which European patents would be translated, although they would also retain the right to require translation of the claims in one of their official languages.

It is estimated that should the London Agreement begin operating, it would cut the cost of translations in Europe by 50%. But although a number of countries have ratified the Agreement, and others have prepared legislation to do so, it cannot come into force until ratified by France, Germany and the UK. The Germans and the British have now signed up but the French have not, as the government has been worried that the Agreement will have an adverse effect on use of the French language. However, following strong representations during 2005 from patent groups and organisations in Europe, there is increasing confidence that the French may be coming round. If it does happen, it will be a move that will be popular in boardrooms across the continent.

European Patent Litigation Agreement

The European Patent Litigation Agreement (EPLA) envisages the creation of a European Patent Court that would have exclusive jurisdiction to hear cases concerning actual or threatened infringements of European patents, and actions and counterclaims for the revocation of European patents, as long as the defendant is domiciled in a contracting state.

To come into force, however, the EPLA needs to be ratified by national governments, something that has been made difficult by the European Commission's reluctance to endorse the plan. Again, however, it seems that during the last year — perhaps as the Community patent became an ever more distant dream — the Commission began to have second thoughts. Certainly the pressure to do so grew. In an unprecedented move in the autumn, for example, 24 judges from courts including the UK House of Lords, Germany's Federal Court, the Italian Supreme Court, the Court of First Instance in The Hague, the Tribunal de Grande Instance in Paris and the Commercial Court of Zurich, urged the adoption of the EPLA.

Computer Implemented Inventions Directive

No review of Europe's patent year would be complete without mentioning the Computer Implemented Inventions (CII) Directive, which finally died an unlamented death in July 2005, when the European Parliament voted by a huge majority to reject it. Since its introduction in February 2002 as legislation designed to harmonise Europe's approach to the protection of computer-implemented inventions, the CII Directive had inspired a debate of increasing ferocity — and some animosity — between those who saw it as an essential exercise in clarifying practice and those who felt it would lead to a US-style system of software patents. Since the European Parliament's decision, the EPO has confirmed it will continue to look at applications relating to software and business methods in the same way as it has done so up to now; meaning that at least some software-related patents will continue to be awarded in Europe. Whether they can ever be enforceable, however, remains very much open to question.

INDIA

Although patent filings in India have gone up four-fold in the last five years, at 17,000 per annum in 2004 they are still relatively low. However, moving forward it is to be expected that this situation will change, as major revisions to the country's patent laws made in 2005 begin to have an effect.

Patents (Amendments) Act 2005

As a result of the Patents (Amendments) Act 2005, pharmaceutical products are now patentable subject matter in India. In putting this legislation on its statute books, India has ensured that it now meets the provisions of the TRIPs agreement it signed when becoming a member of the World Trade Organisation in 1995. Until the new law, India recognized only patents on processes, enabling Indian companies to use alternative methods to manufacture generic copies of drugs that were patented in other countries. India was also required to start collecting drug patent applications filed between 1995 and 2005, and to begin examination of these once the new law had been put into place. It is understood that some 8,000 such applications are currently being dealt with as a result.

Revisions and reactions

The new legislation was hugely controversial in India, and was only enacted after a series of revisions were made to the original draft. These included:

- tightened standards for the granting of patents
- restoration of procedures for opposing patents
- introduction of protection for existing producers of 1995-2005 medicines
- allowance of parallel importation
- limitations on the negotiation of voluntary licences
- expansion of rights to export post-1995 generic medicines produced according to provisions contained in compulsory licences.

Campaigners, however, were not entirely satisfied, and criticised provisions that create rights to patent certain new uses, formulations, delivery systems, combinations of existing products, and minor variations of existing chemical entities. They also disliked the "patent-like" rights for patent applications between the publication and approval of the patent, claiming that this would deter generic entry even in cases where the patent application may later be denied.

For their part, research-based pharmaceutical companies — which have long been pressing for a revision to Indian patent law — have broadly welcomed the changes. They believe that its long term effects will be hugely beneficial for the industry in India, and point out that between 2001 and 2005 there had been a 400% increase in private research and development spending on drugs and pharmaceuticals in anticipation of the reforms.

Much about the new law remains uncertain and probably will do so until it is tested through the courts. There are, for example, significant ambiguities relating to patentability, while compulsory licensing provisions are somewhat vague.

Computer-implemented inventions

Although most of the controversy around the new law related to the pharmaceutical industry, there was also considerable lobbying with regard to computer-implemented inventions. In the Ordinance promulgated by the Indian President at the end of 2004 — which was designed to act as a stop-gap while the full legislation was debated by Parliament — the wording made clear that if an invention was directed at computer software that had technical application to industry, or was coupled with hardware, it could be patentable. However, at the insistence of the ruling coalition regime's leftist parties, this provision was dropped, meaning that the law has now reverted to its original position, namely that computer programs *per se* are excluded from patentability.

Manual of Patent Practice & Procedure

At around the same time the new legislation was approved by Parliament, the Indian Patent Office published a draft Manual of Patent Practice & Procedure designed to create uniformity in the way patent applications are treated in India. Some have pointed out that in giving this as one of the reasons for producing the manual, the Office is indirectly admitting that the country's patent prosecution system has, in the past, tended to be inconsistent, particularly when it comes to examination. In particular, they say, issues relating to the structure and functions of claims have been treated very subjectively.

As a result of the lack of precedents relating to patent law and practice in India, the 14 chapters and three annexes of the draft manual focus heavily on experience in other parts of the world — in particular the US, Europe and Japan (something that has alarmed certain groups, which state the patenting and social environment in these jurisdictions do not reflect the realities in India). Of particular interest is the detailed explanation of patentability criteria, something that is crucial in the light of the new legislation's redefinition of key concepts such as the inventive step.

Parties had until the end of August 2005 to respond to the draft. A finalised Manual, which may reflect some of the concerns raised by respondents, should be published in 2006 and will be a welcome aid to all those looking for clear guidance on how to steer through the patent application process in India.

JAPAN

The very early years of the 21st century were not good ones for the Japanese economy. After the successes of the late 20th century, Japan suddenly found itself with flat growth rates and a declining position in world competitiveness rankings. At the same time, the traditional manufacturing base was being challenged by the advances being made in countries such as China and other countries in the Asian Pacific Rim, all of which were in a position to offer products at lower prices than Japanese companies.

Strategic Council on Intellectual Property

It was against this background that in 2002 the country's Prime Minister Junichiro Koizumi declared that Japan should become a country based on the development and exploitation of intellectual property: only through the creation of valuable IP, he said, would Japan be able to prosper in the global economy. To this end, he convened the Strategic Council on Intellectual Property. This body, which was composed of individuals drawn from the law, science, industry and academia, then produced the IP Strategic Outline.

The Council suggested action in five key areas:

1. The promotion of intellectual property
2. Greater protection for intellectual property
3. Increased exploitation of intellectual property
4. An improvement in public awareness of intellectual property issues
5. The promotion of IP-related human resources

The Outline was followed by a more detailed Strategic Programme for the Creation, Protection and Exploitation of Intellectual Property Rights, and this has been subject to revisions in both 2004 and 2005. Overall, the three years since the Outline was handed over to Koizumi have been busy ones for IP owners and practitioners in Japan, and 2005 was no exception.

IP High Court

In April, for example, a specialist IP High Court came into being. This comprises four divisions which have a total of 18 judges. They hear all appeals relating to decisions taken at the Japanese Patent Office, and also from the Tokyo and Osaka district courts, which have exclusive jurisdiction to hear first instance cases involving patents, utility models and computer programs. The judges are supported by a team of researchers who are able to investigate issues surrounding complicated technical cases.

So far, the Grand Panel of the IP High Court has handed down two decisions, with another one pending for January 2006. Most notably, it ruled in October 2005 in a dispute that had pitted Matsushita Electric Industrial Co against Justsystem Corp over the former's claim that

Justsystem had indirectly infringed its patent covering software relating to a so-called “help mode button” function. The Grand Panel of the IP High Court overturned the district court’s finding that had upheld Matsushita’s complaint and, furthermore, declared the patent invalid on the basis that it lacked an inventive step and could have been developed with technology that was available before the patent application was submitted.

Following the original district court decision, some commentators in Japan predicted that more software patent owners would be tempted to assert their rights against competitors. The decision of the IP High Court makes this a far less likely proposition. (For further information on the IP High Court, visit the Court’s website at <http://www.ip.courts.go.jp/eng/>).

Reducing pendency times

One of the central planks of the IP Strategic Programme is to ensure that the Japanese Patent Office expedites the patent examination process so that by 2013 the waiting period will normally be 11 months, in contrast to the current time of 26 months — which is expected to rise to approximately 30 months by 2008. Key to getting even close to this target is the reduction of the backlog of applications now sitting in the JPO, a figure which is forecast to reach a high point of 800,000 in the near future. To this end, the recruitment of additional examiners has been made a priority and during 2005 an additional net 115 (17 regular and 98 fixed-term) were added to the JPO staff, meaning that the Office now has over 1,350 examiners.

Law for the Promotion of Expeditious Patent Examination

Another area that the JPO has been looking at closely is the outsourcing of prior art searches. While this has been possible since 1989, until recently it was only possible for work to be given to publicly owned organisations. However as a result of the Law for the Promotion of Expeditious Patent Examination, the public requirement was dropped and replaced with a standard that allows any organization to be involved, so long as it meets certain criteria.

These include:

- the completion of training courses run by the National Centre for Industrial Property Information and Training
- that internal security systems have been carefully assessed
- that the financial status of the organisation has been thoroughly audited

Following these changes, in March 2005 private entities were added to the list of approved organizations for prior art search outsourcing, and these have since been given work to do.

Although there is still much to be done at the JPO, there does seem to have been some progress. In 2004, for example, the last year for which there are figures, the JPO’s target was

to perform 235,000 first actions for patent applications within 26 months; the actual figure achieved was 236,000 in 26.3 months. For 2005, the targets are 240,000 within 27 months.

Leading from the top

Although the country faces many challenges, Japan shows that when there is interest in IP at a high political level, action can be taken to improve a system for the better. Prime Minister Koizumi has frequently repeated his aim that Japan be an IP nation. Of course, declarations are one thing — and are a favorite ploy of politicians across the world — the real trick is to put words into action. So far, however, the signs are that this is exactly what Koizumi intends to do: the Prime Minister continues to involve himself in the day to day roll out of the IP Strategic Programme and, to ensure that his government is as co-ordinated as possible when it comes to IP issues, the Cabinet office — which Koizumi himself heads up — has overall responsibility seeing the reform process through.

Japan is an example of what can be achieved once the right people start taking notice of the issues at hand. The country sends out a strong message not only to politicians but also to IP owners themselves: high-level lobbying does work if it is done in the correct way, by the appropriate people. It is no coincidence that the business representatives on the original Strategic Council on Intellectual Property included Hatsuo Aoki, President and CEO of Fujisawa Pharmaceutical Co Ltd, Fujio Mitarai, President and CEO of Canon Inc and Hisamitsu Arai, Chairman and CEO of Nippon Export and Investment Insurance. It is when industry decision makers at such a senior level have a real interest in patents that politicians sit up and take notice.

THE UNITED STATES OF AMERICA

Although the US patent market is never quiet, 2005 proved to be one of the most explosive on record, with a range of crucial developments at the administrative, judicial and political levels.

US Patent and Trademark Office

At the US Patent and Trademark Office (USPTO) the 2005 financial year, which ran from October 1 2004 to September 30 2005, proved to be the busiest yet. Patent applications topped the 400,000 mark for the first time (the exact figure was 406,302, a rise of 7.2% on the previous year). At the same time, the Office granted 165,485 patents, just under half of which went to non-US residents.

In the foreword to the USPTO's 2005 report, Under Secretary of Commerce for Intellectual Property Jon Dudas stated that: "*The volume and complexity of patent applications continues to outpace current capacity to examine them.*" The result of this, he continued, was increased pendency times, so that the overall average time it takes to issue a patent now stands at over

two years; while in some particularly complex areas — such as data-processing technologies — this figure rises to over three years.

21st Century Strategic Plan

Patent pendency and quality were two issues identified in the 21st Century Strategic Plan, put together by James Rogan, Dudas's predecessor at the USPTO. During 2005, the main aspects of the plan continued to be implemented. For example, the Office recruited a further 978 examiners, exceeding the target by 100. It plans to recruit a further 1,000 examiners during the 2006 financial year. Home working is also being looked at, as is group training, which frees up experienced practitioners to spend more time handling examinations.

One area which has yet to be successful, however, is the electronic filing of patent applications. The USPTO target for these was 4% of the total for financial year 2005; the actual figure was 2.2%, with practitioners complaining that the system being used contained too many glitches and was not user-friendly. By contrast, 86% of trade mark applications in the US are now filed online.

Intellectual Property Owners Association survey

The extent of the challenge facing the USPTO was revealed in a survey conducted by the Intellectual Property Owners Association. In the findings, which were made public in September 2005:

- 71.3% of the companies questioned stated that they expect to spend more money on patent litigation
- 51.3% rated US patents as less than satisfactory or poor
- 67.5% believed pendency times will increase
- 25% felt that patent quality is lower than at any point in the last three years, and 28.7% thought it would deteriorate further

In a speech in October, Dudas recognized that the USPTO still had plenty of work to do. But he also stated that applicants themselves could help more. He explained that of the more 375,000 applications received by the Office during financial year 2004, 100,000 were continuations (applications that had been amended after an initial rejection) while 20,000 to 30,000 annual applications are second continuations. Such figures, he claimed, not only affect overall pendency times but also throw into question the quality of many of the initial applications being submitted to the USPTO. Multiple claims, Dudas said, were another problem: 23% of all claims come from just 7% of applications.

Court rulings

In June 2005, the Supreme Court delivered its much-anticipated decision in the *Merck KGaA v Integra LifeSciences I, Ltd* case. This involved the limits of safe harbour provisions under

the Hatch-Waxman Act for the use of third-party patents for the purposes of drug discovery. In a unanimous judgment, the Court held that the provisions were reasonably generous, so allowing pharmaceutical companies the scope to undertake certain types of research even if this was a long way removed from final product development and submission of information to the FDA. However, the Court did not address the issue of so-called research tool patents; neither did it look at the common law research exemption that has potential application in all fields of endeavour. What, therefore, had the potential to be a wide-ranging and highly significant decision, in fact turned out to have only narrow applicability.

The Supreme Court has also announced that it will be returning to patents during the course of 2006. In *eBay Inc et al v MercExchange LLC*, the justices will look at the extent to which injunctive relief should be an option in patent disputes. If the Court decides injunctions should be done away with or even restricted in some way, the patent litigation landscape in the US will be fundamentally altered.

At the end of October, the Court agreed to hear *Laboratory Corporation of America Holdings v Metabolite Laboratories Inc*. Here, the Court will decide: "Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to "correlat[e]" test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result." Its judgment could have a profound impact on the scope of patentability in the area of business methods.

The decision to hear this case came just after an appeals panel at the USPTO had overturned a standard commonly used by examiners to reject business method patent applications. As a result of *Ex parte Lundgren* case, the so-called technological arts test (which states that mathematical algorithms, such as software programs, that do not affect machines cannot be patentable) can no longer be applied. This ruling broadens the scope for business method patents. At least until the Supreme Court hands down its judgment in *Laboratory Corporation of America Holdings v Metabolite Laboratories Inc*.

Away from the Supreme Court, the Court of Appeals for the Federal Circuit delivered its the ruling in *Phillips v AWH Corporation*. It was a case that allowed the Court to clarify its position on claim construction and, as a result, patent specifications will in future take priority over dictionaries and other extrinsic sources. For many, this was the most significant and wide-ranging patent-related decision handed down by a US court during 2005.

Patent Reform Act

Congress is currently debating the proposed Patent Reform Act, which would bring about major changes to US patent law. Among a number of significant provisions the following stand out:

- the current first-to-invent system would be replaced by the first-to-file system used elsewhere in the world
- the scope of wilful infringement would be narrowed, leading to a reduction in the number of cases where triple damages can be applied
- a post grant oppositions procedure would be established
- courts would be compelled to stay injunctions pending an appeal if the stay would not cause irreparable harm to the patentee or the balance of hardships from the stay favour the patent owner.

The Act has been before law makers since June and, having met substantial opposition from a number of well-organized lobbying groups, it looks to be a long way from finding its way to the statute books. Indeed, whether this ever happens is open to debate.

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