TMPDF

Trade Marks Patents and Designs Federation

Review of Trends & Events in Intellectual Property 2002/2003

Putting Industry's View on Intellectual Property since 1920

About TMPDF

The Trade Marks Patents and Designs Federation was founded in 1920 in order to co-ordinate the views of industry and commerce in the United Kingdom, and to make representations to the appropriate authorities on policy and practice in intellectual property matters.

Objects

The Federation's object is to bring about improvements in the protection afforded by intellectual property rights throughout the world, to the advantage of inventors, manufacturers and consumers alike. Today the Federation has over 50 members and associate members, among which are many of the largest companies in the UK, as well as smaller companies. *(For a list of current members see inside back cover.)*

Most if not all industrial and commercial firms use or are affected by intellectual property rights, even if they are not particularly concerned with innovation protected by patents and designs. Nearly all firms own trade marks and copyright material. All are affected by competition law and the rights of others. The work of the Federation is therefore of value to everyone. While many firms leave day to day matters concerning the acquisition of rights to professional attorneys, it is still important to take a direct interest in the policy background, to ensure that proper rights are available, can be secured in a straightforward and efficient way and can be litigated without unnecessary complexity and expense. The Federation is very active in pursuing these needs.

Activities

The Federation initiates proposals and follows all developments at national, European and international levels across all fields of intellectual property. The Federation has a close relationship with the Confederation of British Industry (CBI) and provides much of the professional input on intellectual property matters to the Confederation, as well as representing it in meetings of the Union of Industrial and Employers' Confederations of Europe (UNICE) concerning intellectual property. TMPDF is also an invited observer at diplomatic conferences and meetings of standing committees of the World Intellectual Property Organisation (WIPO).

Contacts

The Federation maintains good contacts with the UK Patent Office, and members of its Council and committees participate in several Focus Groups and practice working groups which advise the UK Government and its agencies on intellectual property matters. TMPDF is also represented on other bodies which advise the European Patent Office. In the UK, it is represented on the Users Committees of the Patents Court and the Patents County Court.

TMPDF also maintains good contacts with parliamentarians both in Westminster and in the European Parliament. In the UK, it has close contacts with the Chartered Institute of Patent Agents (CIPA), with which it jointly organises a core skills course for patent attorneys, the Institute of Trade Mark Attorneys (ITMA), the Intellectual Property Institute and the IP Awareness Group. Internationally, TMPDF exchanges views and maintains good contacts with similar IP user organisations in other countries, notably in Japan and the US.

Membership

The Federation has a Council, which agrees TMPDF policy, and six technical committees, to which detailed consideration of issues is delegated. These deal with Trade Marks, Patents, Copyright and Designs, Litigation, Licensing and Competition Laws, and Biotechnology. Voting members are entitled to a seat on Council, as well as any or all of the six committees. Committee members can join any or all of the six committees. An associate membership is available to those wishing to be informed about developments in intellectual property without joining any of the Federation's committees or Council.

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June 2002 – May 2003

Introduction

The most significant event in the policy field this year was the political agreement on the Community Patent Regulation, reached by the Council of Ministers in March, just when it looked as though the project was doomed. It was a tribute to the determination of politicians that agreement was reached at all, but it came at a cost to applicants – literally, because they would be required to pay to translate all claims into all the official languages of an enlarged EU. It is vital that member states and the Commission work on containing costs so as to make the system attractive to those who at present file European patents for only a few countries.

The agreement includes litigation arrangements that appear a good deal better than in recent discussions, at least at the level they are dealt with in the political agreement. But we remain worried that the political agreement might not be fully reflected in the detailed proposals which have still to emerge and that the transitional role given to national courts before the proposed central court comes into existence may yet turn into something more permanent.

Costs and the judicial procedures are by no means the only details that remain to be worked out. Inevitably, they will be in subsidiary instruments rather than the main Regulation. Since the workability and attractiveness of the system will depend so heavily on these instruments, we hope that, however far member states get with agreeing the text of the Regulation in the course of this year, they hold back on actual adoption until the complete package is agreed. There should be no irrevocable commitment while crucial aspects are undecided.

The Federation has always maintained that efforts to make the Community Patent a success should not harm initiatives to create other improvements in the European patent system. Members of the European Patent Convention have continued work on the European Patent Litigation Agreement, which would allow a single action to decide infringement and validity for parallel European patents. However, it has suffered from doubts as to the attitude of the Commission, which has veered from outright opposition to ostensible indifference: opposition on the grounds that the conversion of the Brussels Convention on jurisdiction into a Regulation has deprived member states of competence to enter into the agreement, and indifference on the grounds that they are not in the business of helping an agreement that would not apply to all member states, since some have indicated they would not join. But the fact remains that, for a decade or more, the vast majority of non-national patent actions will concern European patents. Hence improvements in the European system will continue to be of great importance to all users. They must not be nobbled in order to make the Community Patent more of a runner. Improvements to the European patent system are possible not only in the litigation arrangements but also during the procurement phase, where it remains a great disappointment that the London Agreement on Translations remains adopted yet unimplemented.

The year has seen a number of bodies carrying out studies that question the overall rationale for the intellectual property system. The most important was from the Commission on Intellectual Property Rights, set up by Clare Short's Department of International Development as an independent body of

international membership to advise the British Government on how intellectual property rights could work better for developing countries and poor people. Its report was published in September 2002 and was immediately welcomed by various NGOs, who liked its overall message that intellectual property needed to be cut back. Unfortunately, and this was partly a consequence of the way the report was disseminated, the view got about that the report represented the views of the British Government.

In fact, the Government was considering its response, a process to which the Federation contributed with a detailed paper that both challenged the implications of the report that intellectual property was unhelpful to the developing world and analysed the many individual recommendations. The Government's response finally came in May and was signed by both Patricia Hewitt as Secretary of State for Trade and Industry and Clare Short as Secretary of State for International Development. It was encouragingly robust in its acknowledgement of the value of intellectual property to the developing world. We look at the report and the Government's response in more detail elsewhere in this issue, and here I will say no more than that it started by characterising the report as "a valuable contribution to the debate", which is a polite way of saying that it is – well, far from the last word that some had suggested.

When I became President two years ago, the Government had just changed its consultation system. The Standing Advisory Committee on Intellectual Property, on which the TMPDF was represented, had been disbanded and a new Committee, the Intellectual Property Advisory Committee, had been set up with a different and much more strategic role. Understandably, concerns were expressed that this structure gave the Federation no formal role in the Government's deliberations. But I said at the time I was confident that the Federation would continue to provide the Government with sustained analysis of policy developments, backed up by expert knowledge of their implications for those whose business depends on the intellectual property they generate, and as long as it did so it would remain influential in the new structure. I think that prediction has been well borne out over the time of my Presidency. I offer my best wishes to my successor, under whose leadership I am confident the Federation will continue to flourish and make its voice heard.

June 2002 Roger Broadie

Patents

The Community Patent

Debate about the proposed Community Patent Regulation continued throughout the second half of 2002 and into 2003 under the leadership of first the Danish Presidency of the Council of Ministers and more recently the Greeks. In the autumn of 2002 the European Commission published its proposed framework for the Community Patent judicial arrangements, the key features of which were a unitary Community Patent Court (CPC) of first instance established under the Nice Treaty with appeals to the Court of First Instance of the European Court of Justice. Whilst it was proposed that the CPC would initially consist of a central division seated in Luxembourg, the proposal provided for regional divisions to be created in certain member states as the volume of court work grew. It was also envisaged that the Court would comprise mixed panels of legal and technical judges.
TMPDF provided feedback to both UNICE and the Patent Office on this proposal indicating that we supported it in broad terms. However we also registered our concerns over the workings of the regional divisions (especially if they were to operate under Brussels Convention type rules) and the risks associated in having panels of judges from one legal tradition.
Discussions on this proposal and the other elements of the Community Patent Regulation continued into early 2003 with a number of different options for discussion on the table at different times. During this phase TMPDF was in close contact with the Patent Office either through Council meetings with Patent Office officials or through the Community Patent Focus Group. Political agreement was reached in March and a framework document and a revised draft of the Regulation followed shortly thereafter.

The main features of the political framework are as follows:

1. The Community Patent will be granted by the European Patent Office working within a revised European Patent Convention.
2. It will be possible to file a Community patent application in any official EU language which has been designated for this purpose by a member state. However the application will be translated into an EPO official language before it is examined. The costs of this will be borne by the system (and thus ultimately by users).
3. Upon grant, the claims of a Community Patent will be translated into all official EU languages involving some 19 translations including some minority languages. The cost will be borne by the applicant. No other translation will be required. It remains unclear whether these translations will have any legal significance. The Commission believes that this will represent a significant saving over the costs of an average bundle of European patents currently entering the national phase. However, there are a number of factors which have led us to question this conclusion.
4. It is likely that there will be a time period within which these translations will need to be filed. Germany is pressing for a period of less than two years whilst other countries want something much shorter. This is likely to engender significant political debate.
5. National Patent Offices of countries not having English, French or German as a official language will be entitled to carry out Community Patent searching work under a network of "partnership" agreements which will seek to ensure adequate quality standards. However applicants retain the absolute right to have this work done by the EPO.
6. Overall costs will be set so that 50% of the renewal fees will be retained by the EPO to cover its costs. The other 50% will be distributed amongst the member states according to a distribution key which is likely to be politically controversial.
7. The existence of the CPC is confirmed as a central body without regional divisions. The Court may however act in a peripatetic way if the need arises. The Court itself will come into force by 2010 at the latest. In the interim period designated national courts in each member state may act as competent bodies and will therefore be able to enforce or revoke a Community Patent across the EU. It is by no means clear how many (if any) Community Patents will, in fact, be subject to the jurisdiction of national courts. The language of the proceedings will be the language of the defendant unless the parties agree otherwise.
8. Judges are to have a high level of expertise in patent law and will be assisted by technical experts. It remains to be seen whether this will preclude or minimise the use of expert evidence.
9. There appears to be a commitment to run the Community Patent alongside the existing European and national systems, though there are signs

that the Commission will not strive to help improve these alternatives to its "baby", which casts an unwelcome shadow over efforts to bring in the European Patent Litigation Agreement (page 24).
This outcome is a major disappointment for European industry in the area of costs, which will be much higher than had been originally hoped for. For this reason there is a question as to whether UK industry in particular will use the system. TMPDF along with the CBI has expressed this view to the Patent Office.
Attention is now turning to the details of the proposal and the draft Regulation to ensure that the views of industry on the many remaining points of detail, intended to clarify aspects of the draft Regulation, are taken into account. Unfortunately, comparatively few of industry's suggestions appear to have been adopted to date We understand from the Patent Office that the Commission and the member states wish to finalise the Regulation by year end prior to convening a Diplomatic Conference to revise the European Patent Convention in early 2004. Proposals for EPC revisions and further details of the judicial system are to be published by the Commission over the next few months.

The Patentability of Computer-Implemented Inventions in the EU

Last year's *Trends & Events* reported the publication of the Commission's proposal for a Directive on the patentability of computer-implemented inventions. Broadly, it confirmed the practice of the EPO in requiring patents to be granted for computer-implemented inventions where there is a technical contribution. But it differed in two material ways:

- It restricted the permissible types of claims to two: a programmed computer system or a process carried out in such a system by the execution of software. Though it was not explicit in the draft, it was made absolutely clear that the intention was that claims to programs on their own, as now permitted under European practice, would be forbidden under the Directive.
- It introduced a new exception to match those applying under the copyright in computer programs, particularly those needed for interoperability.

The language in which the requirement for a technical contribution was cast also differed from the EPO practice, because the technical contribution itself was required to be non-obvious. There was also – and this did correspond to EPO practice – a requirement for the presence of a technical contribution as a condition for finding an inventive step. This double reference was particularly troubling to German industry, because it appeared to turn the clock back to earlier decisions under their so-called "core theory". That would have the effect of making it impossible to patent an inventive solution achieved by a novel program if the technical contribution it delivers is of a kind that is obviously desirable, such as an increase in speed or reduction in use of resources.
Over the summer and into the autumn of 2002 the Council Working Group under the Danish Presidency worked hard on the Directive and the Competitiveness Council of 14 November agreed on a text on the basis of which work would be carried forward once the European Parliament had held its first reading.
The main thrust of the Commission's proposal was accepted, with two significant amendments:

- Member states would be allowed to accept program claims, though only if claims of the other types – to a programmed system or program in execution – using the same program were also present.
- A specific article was introduced to make it clear that a technical contribution could not be found merely because a computer was present, and specifically that business or other methods that involved nothing new of a technical nature could not be patented.

The shift towards recognising program claims was very much welcomed by industry, though the Commission maintained a reservation on this change. If program claims are not allowable, patents for computer-implemented inventions become much harder to enforce against the party primarily responsible for causing the infringement, and sometimes relief may not be wholly available because of the territorial nature of contributory infringements.
The second amendment had been proposed by the UK and appears to reflect one of its policy objectives. It is intended to make it absolutely clear (as indeed the requirement for a technical contribution should in any event ensure) that the US approach of permitting the patenting of computer-based business schemes where the novelty is entirely in the business steps will not be accepted in Europe.
The agreed text included some other wording improvements that lessened concerns by many about the possible dangers in the way technical contribution was defined – dangers that were, perhaps, in any case, more theoretical than real. A rewording of the new exception to match those under copy-

right also helped clarify that this was indeed a true exception under the patent rights that matched the exceptions of the Software Directive under copyright, thereby ensuring that a right-holder was not able to use his patents to prevent acts that he could not prevent under his copyright.

Within the European Parliament the lead committee is the Committee on Legal Affairs and the Internal Market, with the Socialist MEP Mrs Arlene McCarthy as the Rapporteur. She had started work even before the Council reached its agreement on the text, holding hearings and issuing a questionnaire exploring various aspects of the need for a directive.

One striking feature of the debate has been the extensive lobbying by a section of the open-source movement that violently opposes the principle of any patent protection that could impinge on the activities of those who write software. It has been conducted in a more colourful way than is the norm in the world of IP policy, to a degree that has probably proved counterproductive with many MEPs. Nonetheless it has had its influence on the Greens and some sections of the PSE (the Socialists). The advisory opinions adopted by the Industry and Culture Committees contained a string of amendments the real object of which was to empty the Directive of any effect, for example by explicitly excluding data processing from the field of patentable activity, or by restricting consideration of inventive step solely to technical features.

Mrs McCarthy, on the other hand, has explained that she supports the main principle behind the Directive, in the interests of legal certainty and because it would be confirmatory of the existing situation. Her draft report contained a series of amendments that were on the same lines as those agreed by the Council. On the other hand, she has also indicated that it was desirable to prevent the European Patent Office from drifting towards a US over-liberality in what is patentable and, unlike the Council, she did not include any draft amendment to make program claims allowable.

The vote on her report has been delayed several times, and at the time of writing is scheduled for mid-June. Predictably, a series of amendments has been tabled that are inimical to the intention of the Directive. On the other hand, there is also a very good amendment proposing to allow program claims that has been tabled as a compromise after a number of MEPs had proposed different wordings, not all of them satisfactory, to allow such claims. Mrs McCarthy has indicated that she would allow an open vote on this point.

The general assessment is that Mrs McCarthy's report is likely to be adopted in her committee, with her amendments and probably also the amendment allowing program claims. There is also is a growing optimism, though no certainty, that the main aspects will be accepted in the Plenary, though whether they will also accept program claims is more doubtful. If they are accepted by the Parliament, so that it and the Council agree on that aspect, it seems quite likely that the Commission would be forced to reconsider its present opposition to these claims.

The TMPDF, in collaboration with the CBI and Intellect, the association covering the IT and electronics sectors, has been heavily involved in lobbying MEPs to support the Directive and program claims. It has also been encouraging SMEs who have applied for patents for software inventions to make their views known in order to counter the suggestion by open-source interests that SMEs do not want patents for such inventions, and letters have gone from these SMEs to MEPs supporting the Directive. Interestingly, they point out that program claims are desirable for SMEs because they ease the enforcement of their patents against suppliers, who are the originators of the infringement. Easier enforcement is something SMEs constantly stress that they want.

Representatives of TMPDF member companies take part in the Patent Office's Focus Group on the Directive, and have seen some of their suggestions put forward by the UK in the Council Working Group and reflected in the Council's text.

European Patents

The Revised European Patent Convention – "EPC 2000"

The 1973 European Patent Convention was revised as what is commonly called EPC 2000 and the new wording adopted by the Administrative Council of the European Patent Organisation in June 2001. The Implementing Regulations were approved in December 2002, thereby completing the provisions for the European patent procedure under EPC 2000.

EPC 2000 will enter into force two years after ratification by fifteen contracting states. As part of their accession in 2002, Bulgaria, the Czech Republic, Estonia, Hungary, Romania, Slovakia, and Slovenia ratified EPC 2000, and therefore ratification by only a further eight contracting states is needed to start the clock for entry into force. It is

expected that EPC 2000 will come into force in 2005 at the earliest, with 2007 being more likely.
EPC 2000 will apply to all European patent applications filed after its entry into force but will only apply to existing applications and patents to the extent specified in transitional provisions.
EPC 2000 includes a new limitation procedure by which the patent proprietor may amend or seek revocation of the patent in a single centralised procedure before the EPO. The patent proprietor is permitted to amend the claims, description and drawings as deemed necessary. The limitation procedure is *ex parte*; however, it is possible for an interested party to submit third party observations. A request for limitation may not be filed while an opposition is pending.
EPC 2000 includes amendments to the status of several time limits. The further processing procedure under existing Article 121 EPC will be applicable to more time periods, thereby reducing the need to resort to *restitutio in integrum* (Article 122 EPC) and the requirement to establish "all due care".
EPC 2000 includes an amendment to the Protocol on the Interpretation of Article 69 EPC. In addition to a change in the detailed wording of the Protocol, an Article 2 on "Equivalents" has been added. This article reads as follows: "For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims". It will be interesting to see how the scope of patents granted under EPC 2000 will differ from that of existing patents, and it is likely that it will be difficult to evaluate the risk of infringement of some European patents until decisions of the courts are available.
The EPC 2000 and the Implementing Regulations have been published by the EPO in a Special Edition of the EPO Official Journal 2003.

The London Agreement on Translations

It is with great disappointment that we have to report that no progress has been made on implementing the Agreement on the Application of Article 65 EPC. This is the optional agreement reached in 2000 which requires EPC contracting states either to waive their ability to require translations completely or do so only in favour of a designated EPO official language. TMPDF believes that this agreement has the potential to offer industry significant costs, especially in the Scandinavian countries. Whilst we understand that the UK would be willing to ratify it, doing so only makes sense if this is part of a "flotilla" of a significant number of countries. One hurdle remains the reluctance on the part of France to participate in this exercise.

Patent Protection in the UK

Contracting Out Search & Examination

In the autumn of 2002 the UK Patent Office consulted users about a proposal to contract out patent search work to the Danish Patent Office and both search and examination to the Dutch Patent Office. The principal reason given for this was to manage the high patent filing levels that the Office is currently experiencing. In its response, TMPDF pointed out concerns it had about how this would work in practice, especially how a common quality standard would be achieved between the three offices. In its reply, the Patent Office tried to allay our fears whilst indicating that they will be going ahead with the project.
The Statutory Order to empower the Patent Office to delegate these functions was adopted on 11 December 2002 and came into force the next day. The order was in entirely broad terms, containing no limitation to the Patent Offices that had been mentioned in the consultation, or even to Patent Offices at all, but the Patent Office gave assurances that there was no intention to contract out except to the Offices they had named.

Patents Act (Amendment) Bill

In the autumn of 2003 the Secretary of State for Trade and Industry will lay before Parliament a new bill seeking to amend the Patents Act 1977. The purpose behind this is to amend the existing legislation to bring it into conformity with the latest version of the European Patent Convention agreed at the Diplomatic Conference in 2000. The Patent Office has used this opportunity to consider also whether any other changes should be made to the Act, especially in the area of statutory inventor remuneration, re-examination and Patent Office jurisdiction to hear infringement actions. In addition to a formal consultation on these issues the Patent Office held two informal open sessions where the views of people could be expressed directly. These session attracted considerable interest, with representatives from TMPDF, the professions, SMEs and private inventors attending. In addition TMPDF submitted detailed written comments produced by an *ad-hoc* group of Patents Committee members. In this response we highlighted the cost to UK industry in extending the

inventor remuneration provisions and the divisive effect it can create amongst inventors and their co-workers. On the issue of Patent Office jurisdiction we argued for simpler and cheaper proceedings in court rather than fragmentation of the system by the creation of another forum. We expect to receive feedback from the Patent Office shortly as to what will be proposed to Parliament.

Regulatory Reform of the Patent System

In parallel to the Patents Act (Amendment) Bill, the Patent Office is planning regulatory reform of the patents system principally to bring the UK into conformity with the WIPO Patent Law Treaty. This will involve for the most part making many of the time limits and formal requirements around filing UK patents more flexible as is the case with modern EPC practice.

One area of major change is likely to be around the section 23 security provisions. The idea is that in most areas of technology UK applicants will be able to first file outside of the United Kingdom without first seeking security clearance from the Patent Office. The feedback we have provided on this latter issue is generally positive but highlights the need to have a framework which is easy to use and provides people with legal certainty. This is of particular importance as the consultation documents suggests that mistakes in this area could attract criminal sanctions.

UK Patent Office Code of Practice

In response to its "Meeting the Future" initiative, the Patent Office put together a committee to discuss the possibility of creating a Code of Practice which would be used to encourage the acceptance of certain standards in working practice by patent professionals in their representation of clients at the Patent Office. The purpose would be to improve the speed of response, shorten the time to grant and minimise the number of iterations between examiners and applicants, ensuring that a proper balance was kept between public interest and applicants' desiderata.

Two meetings have been held so far, in January and March 2003. The initial intention of the Office was to draw up a separate document, entitled Code of Practice, which they were hoping professional representatives would sign up to. It quickly became clear that patent professionals, in representing their clients, did not have the freedom to insist they should comply with certain practices, as they had to follow clients' instructions. The initial approach was also seen as disadvantaging practitioners who had signed up to the code versus those who could act freely in response to client instructions. Patent professional representatives on the committee were also not in favour of yet another separate document to be consulted.

In response to these concerns, the Office has agreed to incorporate items of "best practice" into the Patent Office Practice Manual, with the intention that such practices will be encouraged through the examiners. Future meetings will concentrate on various stages of the patent prosecution process by defining appropriate "best practice" suggestions.

Patent Practice Working Group

The working group continues to meet on a quarterly basis to review patent-related issues and developments and is attended by representatives of the Patent Office, the Chartered Institute of Patent Agents, the International Federation of Intellectual Property Practitioners and TMPDF.

During the period of May 2002 to April 2003, four meetings were held. The main topics which were reviewed were:

- ***Address for service*** when none provided by the applicant. Here the Patent Office contacts the patentee, but does not chase this up when no response is given. Options of contacting the EP representative were reviewed, but no solution was provided.
- ***Contracting out work to other patent offices***. The main emphasis here was the requirement for consistent high quality on identical terms as currently provided by the UK Patent Office.
- ***Translation requirements for granted European patents***. The overall view eventually supported was to encourage a combined approach from France, Germany and the UK, and not to proceed unilaterally.
- ***E-filing***. There has been a frustratingly slow progress towards the electronic filing facility within the UK. The dependency on the European Office's development of the appropriate software, which is involving a number of iterations, is still requiring further upgrades before a pilot system can be taken out to customers.
- The consultation on the ***Patents Act (Amendment) Bill*** (see above, page 10).
- ***Publication of patent applications at 18 months***. Because of a delay in the issue of search reports in some technical areas, a discussion was held about the option of publication without search report, closer to the 18-month period. Since the discussion the Office has monitored the delays and has observed some improvement. Further discussions may happen if the problem recurs.

- ***PCT numbering***. The UK Patent Office had introduced the amended numbering system prior to the official date, and some confusion with WIPO had arisen. This has been resolved.
- ***Late withdrawal procedure***. Some tightening is required, because of internal arrangements. B-specifications are also going to be placed on Esp@cenet on the day of grant, if at all possible.
- A ***customer visit programme*** has been approved, along the lines of that carried out by the Trade Marks Registry. Members of the Practice Working Group were asked to volunteer for a pilot run.
- In addition, review of progress on major IP reforms which impact the UK is a regular topic of the meeting.

Reports of the meetings are available on the Patent Office website, **www.patent.gov.uk**.

WIPO Patent Matters

Patent Cooperation Treaty (PCT)

At the 31st meeting of the PCT Assembly, held during the meetings of the WIPO (World Intellectual Property Organisation) Governing Bodies in September 2002, a number of changes in the operation of the PCT were approved. Probably the most significant is the introduction of "enhanced" international search and preliminary examination, whereby a first written opinion will be established in conjunction with the international search under chapter I, instead of being produced during the international preliminary examination under chapter II. This written opinion will become a preliminary examination report unless the applicant requests examination (and pays the relevant fee) under chapter II. The Federation opposed the mandatory nature of this change, since the experience of its members is that many first written opinions are of poor quality – they are often superficial, misconceived and hostile to the applicant. The only way to partially overcome the adverse effect that such an opinion might otherwise have when the application enters the national phase will be to request full international preliminary examination under chapter II, even when the applicant would otherwise have been content to proceed without such an examination. We are also concerned that delays and costs in chapter I will increase substantially. However, our objections were not heeded, and the change takes effect from 1 January 2004.

Other useful changes were approved by the Assembly – e.g., it should now be possible to reinstate rights if the time limit for entry to the national phase is missed unintentionally or despite due care (the alternative chosen being a matter for the designated office); there will be fee reductions for applications filed in electronic form; all possible designations will now be automatically secured by filing the application; and designation fees will not be separately charged (they will be merged into the filing fee). The Federation, subject to certain comments, indicated that it approved of these changes.

The Assembly also decided that the Working Group on Reform of the PCT should hold two more meetings before the next Governing Bodies meetings in September 2003. At the first of these meetings in November 2002 (the third of the working group), a large schedule of proposals, originating from a number of different countries, was put to the group. As for previous meetings (reported on in last year's *Trends & Events*), the Federation provided detailed comments on these proposals to the UK delegation participating in the meeting and to UNICE. Many of the proposals, while relatively minor, were good, but our main point was that those that were desirable could be achieved through rule changes. It was not necessary to alter the treaty. To do so would cause serious problems for applicants, since for a long time, different countries would be parties to different versions of the treaty, or might even lose their membership, depending on the delays and other problems encountered in ratification procedures.

The fourth meeting of the Working Group takes place in May 2003. A number of proposals concerning detailed changes in the regulations, together with several general discussion papers, are under consideration. Of major interest are discussions concerning quality – both its consistency between authorities and its improvement. The Federation has submitted comments on the proposals and awaits the outcome of the discussions with interest.

Substantive Patent Law Harmonisation

Discussion of a treaty covering substantive patent law has continued in the WIPO Standing Committee on the Law of Patents, with meetings in November 2002 and May 2003. The Federation submitted comments on the revised text considered at the November 2002 meeting. However, there have been few developments of note from the stage recorded in last year's *Trends & Events*. While some of the points that we have made are reflected in the current draft text, many are not. Provisions con-

cerning post-grant limitation have been included, but these do not give third parties a right to intervene. Proposals concerning a so-called "grace period" remain part of the draft treaty, with inadequate third-party safeguards. It remains in dispute whether or not inventions should be required to have a technical character. An anti-self-collision clause for whole contents situations remains in the draft. Unsatisfactory proposals concerning a doctrine of equivalents in claim interpretation remain. We await further developments.

WIPO Patent Agenda

During their meetings in September 2002, the WIPO Governing Bodies approved a memorandum from the Director-General that surveyed the major issues facing the international patent system and containing proposals for future work. These proposals are in two categories:

Improving systems for the grant of patents

The Director-General suggests that work done in other offices relating to search, formalities and examination should be more widely recognised, processes should be more streamlined, duplication of work should be avoided, quality should be addressed, substantive harmonisation of patent law should be achieved rapidly, further common standards, databases and IT systems should be developed, including digital libraries of priority documents, special help to small offices, including the development of regional systems, should be provided by WIPO and member states, and the PCT should be reformed.

Improving the way patents are used

The role of patents as an instrument of public policy should be improved and clarified, information on the value and use of patents should be better disseminated, access to the technical information in patents should be improved, effective enforcement arrangements and strategies need to be developed, and alternative dispute resolution facilities, particularly those of WIPO, should be promoted and enhanced.

A considerable amount of this work is already in progress and the Federation is ready to make suggestions and comments when appropriate.

Biotechnology

EU Biotech Directive Implementation

The implementation deadline for the Directive on the legal protection of biotechnological inventions, the Biotech Directive, was 30 July 2000. Since the last report, only Spain has implemented the Directive, joining the UK, Denmark, Finland, Greece and Ireland, although it is hoped that Norway, Portugal and Sweden will implement it soon. Major difficulties continue to exist in the remaining states. These difficulties vary from state to state and also with the progress of the implementing legislation.

They include the deletion or variation of key provisions including the definition of patentable subject matter, use limitation for genes and an extension of the application of the *ordre public* or morality test to include inventions made in contravention of human rights or the Convention on Biological Diversity, or without prior informed consent.

Future progress in France, Germany, Italy, Belgium and the Netherlands is unpredictable but, even on the most optimistic assessment, they are unlikely to implement the Directive this year. In Luxembourg, there has been no further development since the parliament there called upon its government to renegotiate the Directive.

These difficulties have no bearing on the ability to obtain granted European patents for biotech inventions in accordance with the Directive, since the EPO has already implemented the Directive, word for word. The issue for the EU Commission is therefore less of an IP issue and more of a question of principle that goes to the heart of the EU law-making process. The Commission has initiated the first stages of legal infringement proceedings against countries that have failed to implement: they are under formal notice of legal action and have received reasoned opinions, but the Commission has so far delayed the final step of taking them to the ECJ. It is continuing to work with the relevant states in an effort to "bring them round" and seems reluctant to expedite proceedings unless a member state actually passes legislation that is in conflict with the provisions of the Directive. Even then, it may draw a distinction between a failure to implement part of the Directive and the enactment of legislation in direct conflict with a key provision.

The Commission published a report to the European Parliament on the Directive in October 2002:

http://www.europa.eu.int/eur-lex/en/com/rpt/2002/com2002_0545en01.pdf

The report clarifies the uncertainty that some member states said existed regarding the meaning

and scope of Article 5. It thus also clarifies the obligations of these states in terms of the implementation of the Directive. No state has yet implemented the Directive other than in full and the report should increase the pressure on the remaining states to do this. The European Parliament has announced its intention to debate the report.
The Commission has established an expert group to consider the scope of protection for human genes and the patenting of human stem cells. Priority has been given to the first topic and the Commission's report on this issue should be available towards the end of this year.

Discussion papers and reports

Nuffield Council on Bioethics & Commission on Intellectual Property Rights (CIPR)
http://www.nuffieldbioethics.org/patentingdna/pp_0000000129.asp; **http://www.iprcommission.org/**
Both the Nuffield discussion paper, *The Ethics of Patenting DNA*, and the biotech-related elements of the CIPR report (see page 28) tackle perceived inequalities in the patent system. The Nuffield report acknowledged the broad principles underpinning the system, that the scope of protection is commensurate with the contribution to the art, and that the return to society should be as great as the benefit enjoyed by the patentee, but many of the specific recommendations for legislative changes are made on the strength of anecdotal reports and limited case studies which do not in themselves present compelling evidence for the need for major change. The CIPR report covers all technologies but does tackle biotech-specific issues of use restriction and disclosure of geographical origin.

OECD Report on Genetic Inventions, IPRs and Licensing Practices
http://www.oecd.org/pdf/M00038000/M00038462.pdf
This report represents a fair and balanced analysis of the issues arising in this field. In particular, the report makes the following key conclusions:

- the patentability of genetic inventions is not fundamentally in question,
- the available evidence does not suggest a systematic breakdown in the licensing of genetic inventions,
- in specific areas, such as genetic testing, the numbers and breadth of gene patents are creating some problems,
- there continues to be a large gap between the views of experts and public opinion and this gap needs to be closed,
- while the number of gene patents is rising rapidly and patent thickets and royalty stacking are real concerns, the core of patents that actually need to be licensed is often small,
- uncertainty remains regarding the scope of the research exemption, for example in relation to the clinical use of genetic tests.

Case Law Developments

In the EPO, the President has referred the issue of the patentability of diagnostic methods (Art 52(4)) to the Enlarged Board of Appeal following T-964/99.

In the UK, leave has been obtained to appeal to the House of Lords in *Amgen v TKT*, the erythropoetin case. This follows the Court of Appeal decision that found the patent to be valid but not infringed, and considered interesting questions of insufficiency and equivalence.

In the US, there have been a number of decisions of relevance to biotechnology:

- In *University of Rochester v Searle*, the Western District Court of New York decided that a mechanism of action claim relating to the selective inhibition of Cox-2 enzyme is invalid for failure to meet the written description and enablement requirements. The decision has been appealed against.
- The CAFC heard oral argument in the case between Integra Life Sciences and Merck last November. One key issue relates to the scope of the safe harbour defence provided by Section 271(e)(I) for activities that reasonably relate to the generation of information or data to be used in a submission to the FDA. A related key issue is the question of damages for infringement if the activity does not come within the scope of this provision. The decision is keenly awaited.

In Canada, the Supreme Court has decided by a narrow majority that transgenic animals are not patentable subject matter (the *Harvard oncomouse* case). The Supreme Court also decided that a fertilised egg injected with an oncogene is patentable subject matter on the basis that the various ingredients have been mixed together by a person.
The decision is available at: **http://www.lexum.umontreal.ca/csc-scc/en/rec/html/harvard.en.html**

Trade Marks

The Future of Official Examination on Relative Grounds

United Kingdom

In last year's *Trends & Events* we reported on the consultation exercise that was being conducted by the Patent Office on whether the current regime should be maintained, amended, or dropped, under which all newly filed trade mark applications are searched among the earlier national, Community, and international trade mark registrations valid in the United Kingdom and subsequently, if appropriate, objected to on relative grounds.

The Federation had argued strongly for an abolition of this search regime, and so it was disappointed when it heard, early in 2003, that after due consideration of the results of the consultation, the Government had decided to make no change in the current practice, at least until the 2006 review date provided for by the 1994 Act.

European Union

At the same time, a similar consultation was also being conducted by the European Commission under the terms of Article 39(7) of the Community Trade Mark Regulation. The result of this was published on December 27, 2002 and its conclusion was:

"The Commission has reached the conclusion that the system of searches established by Article 39 CTMR is a costly one, which extends unnecessarily the procedure for the registration of community trade marks, imposes an administrative burden on national offices, the Office and applicants and, despite this, does not provide applicants with a cost-effective and valuable tool to help them to monitor effectively the possible existence of prior conflicting rights."

As a result, the Commission's proposal for making a number of amendments to the Community Trade Mark Regulation, which was published at the same time (see page 16), contained a proposal to completely abolish Article 39 of the Regulation.

At the time of going to press, the Commission's proposals are still under discussion, but the Federation has welcomed a paper presented by UNICE, in conjunction with AIM (the European Brands Association) and MARQUES (the Association of European Trade Mark Owners), supporting the total abolition of Article 39. It is understood that INTA (the International Trademark Association) will also support this view.

The Community Trade Mark

Progress of the Office for Harmonisation in the Internal Market (OHIM)

The number of Community Trade Mark applications filed continued to fall, probably as a result of the world economic downturn:

2000	57,355
2001	48,888
2002	45,184

Similar falls in the numbers of applications received were experienced throughout the industrialised world.

The Office underwent a major re-organisation during 2002. There are no longer separate Examination and Opposition Divisions, but a single Trade Marks Department within which staff in five groups deal with all aspects of a CTM application from filing to registration, including opposition and cancellation. This Department is headed by the newly appointed Mr Hans Jakobsen from Denmark.

Another new appointment was Mr Bruno Machado as President of the Boards of Appeal. Following its comments on the Boards of Appeal in last year's *Trends & Events*, the Federation welcomed this appointment and the reforms to the appeals procedure proposed by the Commission in its proposals for an amendment of the CTM Regulation (see page 16).

Fees

The Office is still running at a surplus, but on current projections it faces a shortfall in income in 2004/2005, with no renewal fees due until 2006 at the earliest. Although some fees are to be dropped under the proposals for amending the Regulation, the level of fees that will have to be charged after the EU enlargement in May 2004 cannot be set until the question is resolved of whether or not searching is to be abolished, or changed (see above).

Jurisprudence

The Court of First Instance and the European Court of Justice, both in Luxembourg, continued to deal with an ever increasing number of trade mark related cases. During the year, the first *inter partes* oppositions reached the CFI from the Boards of Appeal in Alicante.

Proposed Amendment of the Community Trade Mark Regulation

As we report above in connection with searching, in December 2002 the Commission published a proposal to make a number of amendments to the Community Trade Mark Regulation. As well as the abolition of Article 39, this proposal included, for example:

- Changes to who could be a proprietor of a CTM, abolishing the present anomaly that nationals of countries that are not members of either the Paris Convention or the World Trade Organisation could not file a CTM.
- Major changes in the structure of the Boards of Appeal, in the manner in which their members are appointed, and the appointment in appropriate cases of enlarged boards as well as single-member boards.
- Abolition for the need to file a power of attorney.
- A large number of procedural points which include changes relating to: the bankruptcy and insolvency of trade mark owners; refusal on absolute and relative grounds of geographical indications; the division of applications which have been only partly refused or opposed; the apportionment of costs; the revocation of obvious mistakes etc.

All of these proposals are currently under discussion by the Competitiveness Council.

Internet

ICANN

The Internet Corporation for Assigned Names and Numbers (ICANN) spent much of the last twelve months consulting on and later implementing its own reorganisation and restructuring. On 27 March 2003 a new President was appointed, Dr Paul Twomey. On his appointment Dr Twomey stated that he looked forward to enriching ICANN's global relationships and completing its reform efforts.

During the year ICANN held meetings in Shanghai (October 2002), Amsterdam (December 2002) and Rio de Janeiro (March 2003).

As we discuss below, reforms and improvements on which ICANN has been working include a framework for the introduction of Internationalised Domain Names (IDNs) and the Redemption Grace Period, which allows restoration of deleted domains within 30 days in the case of error for .com and .net top level domains. There was also work on policies to improve the accuracy of WHOIS data and timetables for deleting names when registrations expire. Discussions with Regional Internet Registries and ICANN also continued, with the aim of strengthening co-operation and maintaining a stable and responsive system for the allocation of domain names and IP addresses.

Generic Top Level and Country Code Domains

During 2002 the transition of the .org registry from operation by Verisign to Public Interest Registry, a non-profit operator, took place and was completed successfully in January 2003. All of the seven top level domains (TLDs) adopted by ICANN in 2000 are now up and running. It is estimated that the number of generic TLDs currently reserved is approximately 28 million (not including the sponsored TLDs).

Part of the reform proposals was to set up a Country Code Names Supporting Organisation (ccNSO) as the body to address ccTLD issues. This body is intended to develop global and process policy as well as handle ccNSO membership. At present the ccNSO does not represent all the ccTLD managers' views, but work is continuing on setting up a framework.

A registry has been appointed to run the .eu TLD and progress is underway to have a restricted early application process and an effective dispute resolution policy.

At the Rio de Janeiro meeting a paper was presented and discussed at the Public Forum on soliciting proposals and proposed processes for new sponsored TLDs.

Dispute Resolution

The Uniform Dispute Resolutions Procedure (UDRP) continues to be used by IP owners, although instances of obvious cybersquatting appear to have reduced significantly. According to ICANN statistics there are around 730 domain names involved in proceedings that are awaiting a final outcome (as at April 2003). Most UDRP cases are referred to the WIPO Arbitration and Mediation Service, whose statistics also show a general drop in number of proceedings for gTLDs. WIPO also administers the UDRP for certain ccTLDs and the number of proceedings for those remains consistently low. The ICANN Task Force on UDRP did not report on the findings of its survey and review, and consideration is now being given to setting up a new Task Force with a revised remit. Up to 1 April 2003, Nominet, which administers the .uk TLD, has received a total of 852 disputes into its dispute resolution service, which was launched in September 2001. At present 97 remain ongoing. 55% of cases which completed the mediation stage reached an agreement to settle.

The World Intellectual Property Organisation (WIPO) presented to ICANN the so-called WIPO 2 report on naming conventions. This report addresses conflicting interests of right-holders over use of international non-proprietary names and acronyms for intergovernmental organisations (IGOs), geographical identifiers and trade names. WIPO has requested ICANN to modify the UDRP so as to allow IGOs to file complaints and that the short and long names of United Nations member states should be protected against identical and misleadingly similar domain names registered by persons unconnected with the constitutional authorities of the states.

Panellists in dispute resolution and judges in cases are now both more familiar with the respective interests of parties in domain name disputes, but there is still some considerable difference in precedents globally.

Internationalised Domain Names

Over the past few years an Internationalised Domain Name Working Group has been working to internationalise the domain name system at the application layer by standardising a system for the translation of codes used for scripts, symbols and glyphs used in languages other than English so they can be resolved into the existing domain name system. This work culminated in a standards protocol in October 2002. Implementation of this protocol will allow users to use domain names with non-ASCII characters bringing with this benefit concerns about user confusion and new opportunities for cybersquatting.

Before gTLDs can accept registrations of Internationalised Domain Names (IDNs) ICANN authorisation is required. In March 2003 ICANN published a paper on what standards it should apply to authorise IDN registrations; it basically requests compliance with technical standards and collaboration with affected communities and relevant experts. At the Rio de Janeiro board meeting further broad-based consultation and collaborations were recommended to study and develop appropriate language-specific IDN registration rules and policies.

Redemption Grace Period

The Redemption Grace Period (RGP) for .com and .net was introduced in January 2003. The RGP is a thirty-day registry hold period for deleted domains designed to allow registrars to restore names that were deleted accidentally without the intent of the owner. This system was introduced to solve the problem of deleted domains being immediately made available for re-registration. Similar to the principle of late renewal and restoration for trade mark owners, it provides a short time during which a domain name owner can restore his ownership, thereby avoiding the possibility that someone else will acquire a domain name that is still being used, point the address at another site and hold the original owner to ransom for its return. Notwithstanding some problems with the introduction of the service and complaints about the high level of fees charged by some registrars, ICANN plans to roll this out to other generic TLDs.

WHOIS

The ICANN WHOIS Task Force's recommendations in its final report were adopted at the Rio de Janeiro board meeting. The recommendations, including two which aim to enhance data accuracy, reflect considerable input by various interested parties. The introduction of these recommendations by ICANN-accredited registrars will significantly assist IP rights owners in auditing, renewing, and otherwise maintaining their rights, as well as investigating instances of suspected abuse.

Combating Counterfeiting and Piracy

In March 2002 UNICE presented its paper in response to the Commission's November 2000 follow-up to the 1998 Green Paper on combating counterfeiting and piracy in the single market. UNICE's paper had its origins in work done by TMPDF at the turn of the year. It accepted that the follow-up communication and the Green Paper together addressed the most important issues. The aim was to promote the development of a new EC directive to encourage member states to upgrade and unify the measures they offered – a level playing field – to both enforcement authorities and brand owners.

But UNICE pointed out that (1) counterfeiting was not just a problem for brand owners, but extended beyond the private sector, so that the public sector should take the lead in the fight against fakes; and (2) any new measures incorporated in the directive were likely to, in effect, function as reference standards by countries outside the EU and might even become a basis for an amendment of TRIPs. Additionally, it drew attention as the representative of wider European industry to the need to draw a clear distinction between counterfeiting in the conventional sense of a deliberate intention to deceive the consumer, and intellectual property disputes where there are genuine disagreements between the parties as to the scope and validity of a right.

The UNICE paper asked for greater funding, better training and exchange of information, and more awareness campaigns. It also pointed out that attention would need to be paid to the ten candidate countries for membership of the EU, and suggested further study of parallel imports to see what part they played in the distribution of counterfeit material.

At the same time there was work being carried out on possible changes to the existing Council Regulation 3295/94 on the customs aspects of IPR protection. Among the ideas being considered were: broadening its scope to include other IPRs (with an eye to the forthcoming Community Design); the ability to submit applications electronically; a harmonised list of minimum information to be provided by the right-holder; and the abolition of fees.

There was much discussion over what should be done with seized counterfeit goods and the attitude to be taken towards counterfeit items of an apparently non-commercial nature contained in travellers' personal luggage and within customs duty limits. UNICE participated in AIM's Anti-Counterfeiting Committee which prepared a response to DG TAXUD's discussion document.

In July the Commission made available its 2001 statistics regarding counterfeiting and pirated goods seized at the EU's borders. These showed that: counterfeiting is no longer restricted to luxury goods but has now spread to affect virtually all areas of economic activity (there was evidence of industrial-scale production of counterfeit sweets); counterfeit products are routinely sent on roundabout journeys in order to hide their origin; and air transport is now the preferred method of carriage.

In October the Commission proved the earnestness of its intent by releasing its report "Counting Counterfeits", a massive 253-page study defining "a methodology for the collection, analysis and comparison of data on counterfeiting and piracy in the single market." It was said that the report was intended as the basis for discussion, but it seemed that most were put off by its sheer weightiness.

In December the Court of Appeal, in the case of *S v London Borough of Havering*, provided some comfort to brand owners by confirming that Section 92(5) of the Trade Marks Act 1994, which provides that it is a defence for a person charged with an offence under Section 92 to show that he reasonably believed that he was using the sign in a non-infringing manner, imposes a persuasive burden of proof on the accused, as opposed to a mere evidential one. The accused is thus required to prove on the balance of probabilities that he did have reasonable grounds for his erroneous belief. Moreover, the Court said that this requirement was not inconsistent with the rights of the accused under the European Convention on Human Rights (i.e. that he is innocent until proven guilty).

In January this year the new instrument promised by the Commission in its follow-up to the Green Paper on counterfeiting and piracy finally appeared, when the Commission presented its proposal for a Directive on the enforcement of intellectual property rights. As foreshadowed in the follow-up communication, it extends much more broadly than to dealing with enforcement of IP rights subject to counterfeiting and piracy in the normally understood sense, and the Federation's reactions to the proposal can be found on page 24.

Also in January the Commission presented its proposal for a new regulation to tackle counterfeiting and piracy, to replace the existing Regulation 3295/94. Whereas the new Directive is aimed at counterfeit goods circulating within the EU, the Regulation applies to the seizure of suspect in-

fringing goods at the EU's borders. It seeks to clarify the law and to extend it to include new rights such as geographical indications, also to eliminate the differences in approach as between the member states so as to make customs actions easier overall for right-holders.

At the time of writing, the Federation, like most other interested bodies, is still considering the proposal and has yet to make its comments. However, given that the draft appears to address most of the issues raised by the interested parties back this time last year, it seems likely that it will be given their blessing.

Finally, mention must be made of the high-level Business Leaders Alliance Against Counterfeiting, which was launched at the World Economic Forum in Davos in January. The annual subscription runs to tens of thousands of pounds and there is a requirement that the chief executive of a participating company should attend at least one of the meetings every year but, perhaps because of this, press attention has been high, which is half the battle. The alliance is actively looking to increase its membership from the current eleven (Unilever, Procter & Gamble, Gillette, Daimler Chrysler, Philip Morris, BP, Novartis, BAT, Pentland, Allied Domecq and Japan Tobacco) to at least twenty from all industry sectors.

Registration Practice Working Group

When the last issue of *Trends & Events* was published, the outcome of the Trade Marks Registry's consultation on the early abolition of examination on relative grounds was awaited. As reported on page 15, this continued to be the case for most of the following twelve months, but in March this year the Registry announced that the status quo would be maintained at least until the date specified in Section 8 of the Act.

Meanwhile, the Registry has launched a consultation on the reform of the opposition process. This follows initial proposals for a two-tier system made in late 2001. Since then, the Registry has consulted extensively with its legal advisers and the revised proposals may be found at the Patent Office website under the heading "Informal Consultation on Trade Marks Rules". Responses are requested by 26 June 2003. The intention is that the Registry will express a preliminary view on the merits of oppositions under Sections 5(1) and 5(2) before the filing of evidence unless the parties jointly request that this should not happen. If either party wishes to proceed notwithstanding an unfavourable preliminary opinion, it may do so but at its own risk as to costs.

A number of Practice Amendment Notices have been issued during the year, the most hotly debated being PAN 4/02 which sets out the revisions to the Registry's practice following *Baby-Dry*. The discussion of this PAN at Registration Practice Working Group meetings was notable in that some of the changes proposed by the Registry were regarded as altogether too liberal by some of the interests!

The Registry's dedication to achieving the paperless office is evidenced by the quantity and quality of resource they are making available for the purpose. The electronic Trade Marks Journal is available, significant progress has been made towards an electronic filing system and hearings may be booked on the Internet. Improvements to the website, particularly the searching facilities, are planned.

The Registry has met with the Department of Health to discuss the responsibilities that would be placed on them by the proposed regulations on the promotion and advertising of tobacco products. They are particularly concerned by the proposals to regulate brand-sharing.

Relations between the Registry and OHIM continue to be cordial. The Registry seems keen to move towards those aspects of OHIM practice it believes to be better than its own, e.g. shorter terms for responding to official objections, a requirement on an opponent relying on a registration more than five years old to demonstrate use if requested to do so, etc. This year's British Day in Alicante sponsored by the Registry was reported to have been a great success.

Designs

The Community Design

The Council Regulation on Community Designs, which established a new unitary Community Design to be applied for at the Office for Harmonisation in the Internal Market (OHIM) in Alicante, was adopted in December 2001. The Implementing Regulation setting out the necessary procedures was passed on 21 October 2002 (No. 6/2002). Quickly following on from this OHIM began accepting applications for Community designs from 1 January 2003 although the first possible filing date for a Community design application was 1 April 2003.

The key provisions

What can be protected? "The appearance of the whole or part of a product resulting from the features of, in particular, the lines, contours, colours, shape, texture and/or materials of the product itself and/or its ornamentation". The same definition applies to both registered and unregistered designs, with surface decoration not specifically being excluded (Article 3).

What cannot be protected? Features solely dictated by technical function, "must-fit" features, a component part which is not visible during normal use of the complex product and designs contrary to public policy or morality (Articles 8-9).

Novelty. A design lacks novelty if it has become known in the normal course of business to the circles specialised in the sector concerned, operating within the Community (Articles 5, 7).

Individual character. The design must have "individual character", that is the overall impression that it produces on the informed user must be different from the overall impression produced by an earlier design (Article 6).

Grace period. Disclosure during the 12-month period preceding the date of filing or the priority date (if claimed) of the application does not destroy the novelty or individual character of the design (Article 7).

Duration. Five years as from the date of the filing of the application, renewable for further five year periods up to a total of 25 years from the filing date (Article 12).

Right to the Community Design. The right to the design belongs to the designer, his successor in title or his employer (unless otherwise agreed under national law). The designer shall have the right to be cited as such (Article 14).

Scope of protection. The holder of the Community design shall have the exclusive right to make, offer, put on the market, import, export and stock the product in which the design is incorporated (Article 19).

Multiple applications. Several designs may be combined in one application. Except in cases of ornamentation, this possibility is subject to the conditions that the products in which the designs are intended to be incorporated or to which they are intended to be applied all belong to the same class of the Locarno Classification (Article 37).

Deferment of publication. The applicant may request, when filing the application, that the publication of the registered Community design be deferred for a period of 30 months from a date of filing the application or, if priority is claimed, from the date of the priority (Article 50).

Community Design Courts. member states are required to nominate by 6 March 2005 a limited number of courts to consider issues of infringement and validity of Community Designs (Article 80).

The Regulation also provides for the exhaustion of Community Design rights (Article 21), prior use in respect of Community Designs (Article 21) and an interim solution on the repair issue until it is harmonised at Community level, under which parts that can be used as spares would be registrable but not enforceable against supply as a spare (Article 110).

Other information

The official fees for filing a Community design application are approximately €350, although these can vary, for example according to the number of designs filed in the application. However, the fees are low in comparison to the costs for filing of individual applications in each EU member state.

News from OHIM is that at the moment there is a six week delay in processing Community Design applications as the demand from 1 April has far exceeded expectations.

Finally, unregistered Community design rights arise automatically when a design is created and came into existence on the 6 March 2002. Unregistered design rights subsist for three years from the date the design is made available to the public in such a manner that people specialised in the relevant sector within the Community would reasonably be expected to be aware of it (Article 11). As in the UK, an unregistered design can be infringed only if the use concerned results from actual copying of the design.

Designs Practice Working Group

The Federation is represented on the Designs Practice Working Group, which has met four times during the year. Important topics of discussion have included the European Designs Directive, the Community Designs Regulation, its Implementing Regulation and the impact of these European developments on UK design law.

Full minutes can be found under **http:// www.patent.gov.uk/design/notices/practice.htm**.

Copyright

Copyright Harmonisation in the European Union

The main surprise of the year has been what has not happened, namely implementation of the Copyright Directive, the Directive on the harmonisation of certain aspects of copyright and related rights in the information society, which was due to be implemented by 22 December 2002. The United Kingdom was not alone in missing the date. In fact, only Denmark and Greece, the outgoing and incoming Presidents, achieved it, and only now are other member states beginning to complete their implementation. The Commission has let it be known that it will tolerate member states' delays at least up to the end of July, and the UK now appears to be aiming for that date, but some member states are likely not to implement until later in the year, or even next year.

In August 2002 the UK issued a much-delayed consultation paper on its implementation, with draft text for the core amendments. In view of the short time-scale the text introduced the minimum changes needed to adapt British law to the mandatory requirements, though it left open the possibility of further consultations on optional features, where the government appears to believe that the route of implementation via secondary legislation would remain open to it even after implementation of mandatory features.

On exclusive rights, the consultation proposed to implement Article 3 by introducing a new restricted act of communication to the public by electronic transmission, which would subsume the present restricted acts of broadcasting and including in a cable programme service. In the TMPDF's view that approach could lead to a welcome simplification of the present law, and especially the cable programme service aspect, which was made to cover some rather disparate types of activity in the 1988 Act.

As is usual in copyright, the exceptions have proved contentious. The draft makes no change in principle to the British structure of exceptions. In particular, it has rejected the suggestion by some sections of the content industry that compliance with Article 5.5 of the Directive, which is a version of the Berne three-step test, should be brought in as an additional requirement for the UK exceptions, so that someone who claims to benefit from an exception would have to show the court that he meets its requirements. The government has taken the view that the UK exceptions are cast in such a way that they inherently meet the requirements of Article 5.5, which therefore does not need to be made an additional test.

The one mandatory exception, Article 5.1, which includes certain technically necessary copies, has been implemented verbatim. Sadly but predictably in view of the wording of the Directive, the UK exception of fair dealing for research will no longer be available if the research is for a commercial purpose.

The UK has not extended its present narrow private copying exceptions, principally the recording of broadcasts for time-shifting, and correspondingly has not seen the need to introduce levies on recording media or equipment as a way of achieving the "fair compensation" that Article 5.2(b), the basis for private copying exceptions, requires. That follows the success of the UK in ensuring that the concept was sufficiently nuanced in the Directive, especially the recitals, to leave room for that outcome.

To meet the requirements of Article 6, which deals with the protection of technical measures, the UK has had considerably to strengthen Section 296 for works other than computer programs. No longer will it apply only to the supply of the means to enable the overcoming of technical protection with the requisite knowledge that it would be used to make infringing copies. The act of circumvention itself, and the supply of circumventing devices for any purpose, will become unlawful. The Directive deemed this heightened level of protection necessary because, in the digital world, the consequences of even a single unlawful copy can be disastrous. But it was balanced in the Directive by a requirement that the benefit of certain socially desirable exceptions should nonetheless be made available, by some means or other, to those entitled to benefit from it (except, rather obscurely, when the work was made available as part of an on-demand service). There is also an option, which the UK is taking up, to apply the same solution to private copying exceptions. The UK is proposing a code to allow those who should be able to benefit from the exceptions but are thwarted by technical protection to apply to the Secretary of State for relief, though it does not appear fully worked through in the draft.

On the Continent, much of the debate about implementation has been about the interaction be-

tween private copying, levies and technical protection. Levies are treated in, for instance, Germany as a payment for a statutory licence to make private copies that would otherwise infringe (and not, despite the misunderstanding of some in this country, as compensation for ineradicable piracy). The Directive indicates, though with no great clarity, that technical protection should render levies unnecessary. The reasoning is that technical protection, in conjunction with digital rights management systems, will allow direct licensing by individual right-holders, thereby removing the need for levies, which are fixed sums unrelated to actual use and go universally to collecting societies as intermediaries (who thus have a vested interest in their perpetuation). But there is minimal guidance on how the various factors are to be taken into account.

In the UK, one of the main hold-ups appears to be the new restricted act of communication to the public by electronic transmission. A very complicated arrangement has been proposed that does not map easily onto the article it implements, mainly because of the need to ensure that only the appropriate exceptions apply to each of the various acts it embraces. But officials recognise that the wording is not yet right. Various constituencies are unhappy. The content industry has concerns about the way interactive services are handled. Broadcasters are dissatisfied about the disappearance of the cable programme as a separate class of copyright work. Though that change appears sensible on its face, given that the existing law gives protection to material totally lacking in copyright originality, it would deprive broadcasters, as opposed to the underlying right-holders, of the ability to take action against those who make unauthorised use of their Internet broadcasts of third-party material. The TMPDF was concerned that the fundamental act, in the information society, of putting a page on a web-site was not clearly dealt with; indeed, it seemed to be being regarded as a species of broadcast.

Another important area that has led to differing inputs is technical protection. The content industry wants more criminal penalties, so that the mere act of circumvention of a technically protected work by a private individual, regardless of what happens to the copies he makes, would be a criminal offence. It also objects to some of the detailed departures from the wording of the Directive, and criticises the absence of any specific provision for the grant of injunctions against intermediaries who are sheltered by Article 5.1. From the opposite wing, there has been vocal lobbying by some academics that the Directive would make cryptographic research impossible. There is a recital to the effect that technical protection should not hinder such research; the problem is that there is no indication in the articles as to how that intent could be delivered.

We now await publication of what is likely to be the final form of the regulations.

New UK Legislation

The year did see two new pieces of primary legislation impacting copyright. Both were introduced as private member's bills to amend the Copyright, Designs and Patents Act 1988, and both received government support.

The Copyright, etc. and Trade Marks (Offences and Enforcement) Act 2002 was introduced by Mr Vincent Cable MP and received Royal Assent on 24 July 2002. For copyright, it brought the criminal penalties into line with those for criminal trade mark infringement, increased the search powers of the police and gave greater rights to obtain forfeiture of infringing copies and masters.

The Copyright (Visually Impaired Persons) Act 2002 was introduced by Rachel Squires MP and received Royal Assent on 7 November 2002. It provides new copyright exceptions that, in defined circumstances, permit works to be converted into a form accessible by the visually impaired.

Litigation

European Patent Litigation Agreement

Work in the framework of the European Patent Organisation (EPO) on a litigation protocol, which would provide a common jurisdictional system with a common court for the litigation of European patents, continued during 2002 and 2003, despite some misgivings as to its legality. The European Commission has taken the view that, following the entry into force of the Brussels Regulation (Regulation 44/2001 on jurisdiction and the recognition and enforcement of judgements in civil and commercial matters), the member states of the EPO that are also members of the European Union do not have competence to negotiate and enter such a protocol. It would be up to the Commission to propose and negotiate such an arrangement if it were convinced that it was in the interest of the Union. The Commission's attention is focussed elsewhere, on the jurisdictional arrangements of the Community Patent Regulation (see page 7), and moreover it does not consider that efforts to establish Community-wide jurisdictional arrangements for European patents would command support from all Community member states. A number of member states however are not convinced that competence has been transferred to the Commission and have continued with discussions on the form that the protocol should take. It is understood that the Commission will wait for the final results of the work to appear before deciding on its attitude to the protocol.

As reported in last year's *Trends & Events*, a sub-group of the EPO Working Party on Litigation had responsibility for preparing the draft protocol in treaty language. The sub-group received particular assistance from Mr Jan Willems, a member of the EPO Boards of Appeal who had formerly been a judge in the Netherlands. During 2002, the sub-group considered a fourth draft of the protocol prepared by Mr Willems and instructed the European Patent Office to draft the results of its discussions as a draft "European Patent Litigation Agreement" for consideration by the full working party. The draft was presented to the working party in December 2002. As compared with Mr Willem's drafts, in particular the third, the draft agreement omitted a large amount of procedural detail. These matters are to be left for rules of procedure to be negotiated after the agreement has been adopted, presumably because it is extremely difficult to secure agreement on them at this stage. The working party considered the draft not only at its meeting in December 2002, but also in May 2003, but, so far as we are aware, has yet to finalise the draft.

The Federation has submitted comments on the draft Agreement. It supports the basic concept of the litigation system to be set up under the Agreement, under which it will be possible to bring a single action concerned with infringement and validity for all those contracting states for which a given European patent has been granted before a centralised European Patent Court having first and second instances. However, it is concerned that crucial aspects of the system, such as how cases will be allocated to regional divisions of the court, the establishment of evidence, the role of (expert) witnesses, conditions for injunctions and other protective measures, the procedure for appeals, and other important matters, have not been dealt with, and that the rules of procedure, which should deal with these and many other issues, will not be established until after the Agreement has entered into force. It seems to us that the Agreement should not be adopted before users have seen and commented on the draft rules of procedure. The Federation is concerned, too, about the qualifications of judges – the majority of whom will not be expected to have any technical background – and the language of proceedings before the divisions of the court. The Federation has also submitted a number of points concerning the detailed provisions of the draft Agreement and of the draft statute of the court. It looks forward to rapid progress in the next months in EPO circles towards resolving the outstanding difficulties.

Proposal for a Directive on Enforcement of IP Rights

In October 1998, the Commission issued a Green Paper on combating counterfeiting and piracy in the single market. Following lengthy consultations, in January 2003 the Commission published a proposed Directive on measures and procedures to ensure enforcement of intellectual property rights.

The Commission sees harmonisation of remedies as a logical extension of harmonisation of IP rights

and the introduction of Community rights. Such harmonisation is intended to reduce distortions to competition, promote free movement, promote innovation, and, by assisting in the fight against counterfeiting and piracy, protect consumers, employment and tax revenue.

The proposed Directive appears to seek to incorporate best practice of the various member states into a harmonised system of remedies and procedures. Its principal aims are to remove the economic benefits of infringement from the infringer by ensuring that remedies are available that are fair and equitable, not overly costly or complex and do not involve unnecessarily harsh time limits or delays. It also seeks to ensure that "penalties" for infringement are available which are effective, proportionate and deterrent.

To this end, the proposed Directive sets out a number of procedural mechanisms and pre- and post-trial procedures and remedies which member states are to make available to IP owners. The remedies are also to be available to rights management and similar bodies.

Pre-trial procedures that must be available include such measures as pre-trial injunctions, seizure orders, orders permitting access to banking, financial and other information and asset-freezing orders.

Post-trial remedies include injunctions, damages and accounts of profits, destruction, costs and publicity orders.

Although welcome, the proposals are in several respects flawed. For example, the drafting is such that in many cases the objective of depriving the infringer of the benefits of the infringement may not be achieved.

More important, the Directive is unlikely to achieve significant harmonisation in practice as, although it obliges member states to make the procedures and remedies available, in most circumstances it leaves the question of whether or not to apply the procedures and remedies to the courts without giving any guidelines as to when they should be applied. Although it is clearly inappropriate to set out strict rules as to when procedures or remedies should be applied, if the Directive does not lay down some, it is likely that different member states will apply it in different ways thus leading to minimal harmonisation.

Most troublesome, however, is that the proposed Directive requires that "serious" infringement of IP (defined as being intentional and committed for commercial purposes) should be a criminal offence.

Sanctions are to include fines and confiscation of infringing goods (or goods of equivalent value) and, "in appropriate cases", a ban on engaging in commercial activities, judicial winding up and a ban on access to public assistance and subsidies.

This provision appears to derive from the genesis of the proposed Directive as a measure to combat counterfeiting and piracy. However, the provision is not restricted to counterfeiting and piracy (indeed those words do not appear in the operative part of the proposal), but applies to all forms of intentional infringement of any IP committed for commercial purposes. "Intentional" is not defined.

The problem this provision gives rise to is perhaps most evident in the patent field. For example, parties who proceed on the assumption that there is a reasonable but not definitive argument that a patent is invalid, or who test the scope of a patent claim, are part of the competitive dynamic which benefits the consumer and encourages innovation. Similar problems can arise with other forms of IP.

To impose the risk of criminal sanctions on parties who seek to innovate and in doing so test the boundaries of an IP right (at least without defining with absolute clarity when those sanctions will be imposed) will have a chilling effect on competition.

TMPDF will be involved in the consultation process as the Directive proceeds.

IP Court User Group

TMPDF represents the views of UK industry on the IP Court User Group, which is one of the main ways which the Patents Court and Patent County Court Judges receive feedback from users of the system. During the year comments have been provided on the new Practice Directive for IP litigation and on proposals for general and specific Pre-Action Protocols. TMPDF has also led a sub-committee of this group looking at ways of simplifying IP litigation in situations where either the parties want it or the court so directs. The outcome of this has been the creation of an abbreviated procedure avoiding disclosure and experiments and involving only very limited expert evidence. This procedure has now been included in the Patents Court manual and has been available to litigants since the beginning of April.

Licensing and Competition Law

The Technology Transfer EU Block Exemption Regulation 240/96

This Block Exemption has been found useful by many IP practitioners wishing to draft patent and know-how licensing agreements which are clear of Article 81 of the Treaty of Rome (the former Article 85), and which are therefore enforceable.

The Block Exemption has until 31 March 2006 to run, but the European Commission has been contemplating its replacement before that date. A questionnaire was issued in 2001, to which TMPDF responded, and then an "Evaluation Report", to which TMPDF responded in April 2002.

TMPDF's principal concern was that the Commission was evidently minded to include in the replacement Regulation market share tests applying in circumstances where there were none in 240/96. In particular, it was minded to deprive any two competitors, one of whom wished to license the other, of the benefit of the Regulation if their combined market share exceeded 25%. This is of obvious concern for large companies, whether licensing each other or licensing small companies. It could possibly affect agreements involving only smaller companies, for the nature of patent protection on a significant invention can be to procure a 100% market share for the patentee and his licensees.

However, all that has happened in the year under review is that the Commission has published the responses to the Evaluation Report (including the Federation's response). On the market share issue, they acknowledge that a group of respondents took the (TMPDF) view that no extra market share tests should be included in the replacement Regulation. However, others, including the UK Office of Fair Trading, thought that the 25% limit was "reasonable".

The Office of Fair Trading (OFT) Guidelines on IPR under the Competition Act 1998

At the time that the Competition Act came into force, the OFT promised guidelines on various subjects including intellectual property. In late 2001, a draft guideline was issued on which TMPDF commented in February 2002 and then again in May 2002 as part of a CBI delegation to OFT.

The Competition Act 1998 seeks to control any anti-competitive behaviour which, being national in character, is *not* controlled by Articles 81 and 82 of the Treaty of Rome. Chapter I of the Act deals with agreements and concerted practices, and corresponds to Article 81 (the former Article 85), while Chapter II of the Act deals with abuse of a dominant position and corresponds to Article 82 (the former Article 86).

The draft guidelines issued on intellectual property by OFT in respect of Chapter I included a 25% market share test matching that proposed by the Commission for the replacement block exemption, and TMPDF objected to this.

TMPDF also objected to the guidelines in two further respects:

- The guidelines on both Chapter I and Chapter II sought to be too broad, treating technology (including software), brands, and artistic/cultural works as if they presented identical public policy issues, which they do not.
- In the treatment of the Chapter II prohibition, OFT suggested that IPR relating to "a product or service which is essential to the exercise of the activity in question" should be subject to compulsory licence. This, in the case of patents, would erode rights that are granted only on the basis of merit (novelty, inventive step, etc.), and in respect of which Parliament has already considered compulsory licensing in enacting Sections 48 to 54 of the Patents Act 1977. OFT had made this suggestion purportedly following two EU cases under Article 82 (*RTE*, commonly known as "Magill", and *IMS Health*), both of which involved very special circumstances and were non-technological, and both of which were concerned with copyright, not patents. TMPDF's view is that OFT was not correctly following these cases, the later of which was in any case still to be finally decided.

In September 2002, OFT published the responses it had received, and stated that the guideline would be redrafted and available for consultation in spring 2003. It stated that the redraft would give

due weight to any relevant developments in EU competition law. It also stated that, until the guidelines were revised, "questions as to how the Competition Act 1998 applies to IPR should be considered, among other things, by reference to the existing OFT draft IPR guidelines". This latter comment seems unhelpful, if one considers, for instance, the discrepancy between the "existing draft" and the *current* EU Regulation 240/96 in respect of market share tests.

Replacement of Regulation 17/62 by Regulation 1/2003

In this case, something more definite can be reported. The replacement of Regulation 17/62 by Regulation 1/2003 on 1 May 2004 will change the way in which Article 81, in particular, operates.

The effect of Article 81 is that agreements caught by Article 81(1) are enforceable only to the extent that they are declared inapplicable ("exempted") under Article 81(3). Article 81(3) provides for such an exemption, for instance, where the agreement promotes production of goods or promotes technical progress.

For the last four decades, however, under Regulation 17/62, an Article 81(3) exemption has been available exclusively from the European Commission. An agreement *not* notified to the Commission and caught by Article 81(1) has therefore been unenforceable even if, had it been notified, the Commission would have exempted it on its merits.

The result of this arrangement has been a proliferation of notifications by companies, swamping the Commission, and the adoption by the Commission of block exemptions as a means of reducing the need for such notifications. By way of example, the Technology Transfer Block Exemption is a Commission Regulation (240/96) drafted on the assumption that sole and exclusive licences are generally caught by Article 81(1); it specifies conditions under which the Commission exempts such a licence under Article 81(3) without its having actually to be notified.

The new system from 1 May 2004 will allow Article 81(3) to be applied (i) by national courts and competition authorities as well as by the Commission and (ii) at the time that enforcement of a contract is sought, with retrospective effect. This is to be welcomed as a matter of justice and practicality. Block exemptions will still be able to be relied on under the new system, but it is noteworthy that the trend is in some respects for them to become less generous (see above, and the comment in last year's *Trends & Events* on block exemption 2790/99 covering, *inter alia*, distribution agreements). This trend will increase companies' uncertainty about the enforceability of their agreements, despite the replacement of Regulation 17/62.

Reviews of the IP System

Report of the Commission on Intellectual Property Rights ("CIPR") and the UK Government's Response

The CIPR was set up by the then UK Secretary of State for International Development, Clare Short, in May 2001. It was independent of UK Government. Its Terms of Reference included to consider:

- how national IPR regimes could best be designed to benefit developing countries within the context of international agreements, including TRIPs;
- how the international framework of rules and agreements might be improved and developed.

The CIPR generated a limited amount of new research, considered existing literature and held open and closed evidence gathering hearings.

The CIPR published its report on "Integrating Intellectual Property Rights and Development Policy" in London on 12 September. The report considered the effect of a wide range of IPR-related issues on development, and did so by reference to discrete topic areas including access to medicines, food, agriculture and biotechnology, copyright, software and education, patent systems and the international IP architecture.

The overall tone of the report was negative about the impact of IP in the developing world. It suggested that expansion of IP rights is unlikely to benefit most developing countries or to help poverty reduction, and argued that what it saw as the "one size fits all" approach of TRIPs was inappropriate. The costs of strong IP were regularly referred to; the benefits were regarded as debatable or marginal.

Although many of the recommendations of the report on their face seemed unobjectionable, when read in the light of the underlying tone, which concentrated on the alleged costs of IP, many felt that the report urged adoption by all developing countries of the lowest standards of IP compatible with TRIPs and, indeed, revision of TRIPs. Certainly, the report was welcomed and trumpeted by many NGOs and developing countries which are hostile to TRIPs.

TMPDF submitted detailed comments on the report and was represented at a meeting with the Patent Office at which it was discussed.

The UK Government response to the CIPR Report was published on 7 May. Although the Government accepts many of the CIPR's recommendations, it does not adopt the tone of the CIPR Report.

The Government said that the CIPR "may have interpreted the available evidence in a way that understates the impact of IP in developing countries. For example, too little emphasis seems to be placed on the benefits that may accrue in countries such as India, China and Brazil from implementing TRIPs-standard IP protection". The CIPR evidence was described as being open to differing interpretations.

The CIPR's analysis of the history of IP implementation by developed countries was described as "of interest" rather than justifying (as the CIPR had implied) that developing countries should selectively implement IP protection when they felt best.

These comments implicitly undermine much of the CIPR's analysis and the tone of its report.

The Government frequently reiterates the importance of TRIPs. It believes that "IPRs can play a vital role in the course of the development process for developing countries today, just as they did, and continue to do, in the UK, other developed countries and the most successful developing economies". By encouraging developing countries to "decide for themselves if accelerated compliance with TRIPs or adoption of stronger IPR rights than TRIPs requires might be beneficial for their own development", the Government's response challenges the CIPR's suggestion that strong IPR is generally detrimental to development. In effect, it says that there can be advantages to adoption of more than the minimum standards required by TRIPs which developing countries should consider in framing their laws.

The Government "stress[es] that [it] remains firmly committed to the effective protection of IPRs in order to stimulate continued innovation and creativity".

Overall, the Government's response goes a long way towards restoring balance to the debate, something that was lacking from the CIPR's analysis and report. Several of the NGOs which vocally supported the report have expressed their concerns about the Government's response.

Concerns had been expressed that, before the Government issued its response, the CIPR Report had been widely distributed and that little attempt had been made to ensure that the report was seen as an independent report, rather than a UK Government-endorsed report. The Government has indicated

that it will distribute its response to those who received the report.

- The ***Royal Society*** also conducted a study in the course of the year on possible improvements in the intellectual property regime, to be considered from the viewpoint of its impact on science. The Federation responded with its views. The eventual report does contain a clear acknowledgement of the importance of intellectual property as a stimulus to research and development, but there has been disappointment that various of its recommendations, especially for patents, would nonetheless reduce the effectiveness of intellectual property and make it more difficult for industry to justify investment in the development of new products.

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs)

Since the WTO Ministerial Conference in Doha in 2001, efforts in the TRIPs Council have been focussed on geographical indications and the issues of compulsory licensing for export.

As far as geographical indications are concerned, strongly held views continue to divide the WTO between those, including the EU, who seek to implement strong protection for wines and spirits (and to extend the scope of geographical indications to foodstuffs) and those, including the US, who wish to see both the strength and scope of protection more limited. Although some progress appears to have been made, it remains to be seen whether agreement on key issues can be reached by the time of the Cancún Ministerial Conference in September 2003.

More public have been the negotiations on paragraph 6 of the Doha Declaration (compulsory licensing for export). The Doha Declaration, in addressing some of the flexibilities in TRIPs, stated that TRIPs does not limit the grounds for compulsory licensing. However, Article 31.f TRIPs provides that compulsory licences must operate predominantly to satisfy the domestic market of the granting country.

Countries able to manufacture a medicine can, therefore, utilise compulsory licensing to satisfy domestic demand. However, for countries without the capacity to manufacture, a compulsory licence may be of no practical value as domestic manufacture will not be possible and countries able to manufacture are not permitted to grant a compulsory licence to manufacture wholly for export.

The TRIPs Council was instructed, in paragraph 6 of the Doha Declaration, to address the problem faced by countries with insufficient or no capacity to manufacture a medicine and to recommend a solution by the end of 2002.

Resolution of this issue is seen by some as an indication of whether the developed world is serious in addressing developing-world concerns within the WTO scheme more generally in the context of the Doha Round.

From the outset of the discussions, four issues were controversial. How is lack of manufacturing capacity to be determined? What products should be the subject of the solution and what countries should be allowed to import under the solution? What measures should be included to safeguard against abuse and to prevent diversion of products produced under any compulsory licence?

Those seeking to limit the scope of the solution pointed to the fact that the Doha Declaration arose from the scourges facing the poorest countries arising from HIV (in particular), TB and malaria, and argued that the solution should be limited to products for these diseases (and diseases of similar scope and gravity) and that only the poorest countries should be able to avail themselves of the solution. They argue that a broad solution would, in effect, undermine TRIPs for the pharmaceutical industry by allowing extensive compulsory licensing.

Others argued that the Doha Declaration referred to public health in general and that to limit the countries which could import under the solution would be to discriminate between countries which did and did not have manufacturing capacity.

Various proposals to limit the scope of the system could not be agreed. On 16 December 2002, the Chair of the TRIPs Council proposed a text that would allow all countries without manufacturing capacity (a criterion to be self-assessed) to import all medicines needed to address public health concerns and which included limited measures to guard against product diversion.

That text, which was not satisfactory from the perspective of the pharmaceutical industry, was acceptable to all WTO members except the Untied States which continued to hold out for some limitations to its scope.

Since then, various compromises have been floated formally or informally without success. It remains to be seen whether the issue can be resolved before Cancún or whether issues relating to TRIPs and medicines will feature as highly at Cancún as they did at Doha.

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