INTELLECTUAL PROPERTY, INNOVATION AND COMPETITIVENESS A MANIFESTO FOR THE CHEMICAL INDUSTRY[1]

23 September 2008

CEFIC believes that Intellectual Property (IP) is a topic of great importance to not only innovation and trade but also generally to the competitiveness of the chemical industry. The European chemical industry is one of the European Union's largest business sectors a major employer and has as its core the commercialisation of new technologies, products and processes. We believe IP to be an essential component of our long term business sustainability.

For over a hundred years the European chemicals industry has had a record of bringing new products to the market place. Products, including plastics, fibres and feed, which in many areas have transformed the life styles and well-being of consumers.

Converting new ideas into useful and beneficial products however is not easy. It is often a speculative business involving the expenditure of significant cost and resource to achieve a business outcome which in the early stages is far from certain.

IP play a key role in supporting all sectors of the chemical industry in their attempts to bring new products to consumers. In fact it is fair to say that if the IP system did not exist, the conversion of new ideas into useful products would be significantly inhibited.

> The European Inventor of the Year Award was jointly instituted by the European Commission and the European Patent Office (EPO) in 2006 for the first time.
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> Chemical inventions have always been well placed in the "European Inventor of the Year awards". These awards recognize inventors and innovations that have made a significant and lasting contribution to technical development in Europe and beyond and thus have strengthened Europe's economic position.
> For example, in 2007 the award for "SMEs/Research" was granted to an Italian team for having invented biodegradable plastic from starch; such plastics can be used for instance in eco-friendly refuse bags. These bio-plastics are renewable, recyclable, reusable and they degrade within three to eight weeks in a regular compost pile.

This Manifesto sets out our needs and aspirations for IP in Europe to improve the competitiveness of the chemical industry over the next decade. We hope it will give clarity and direction to policy makers working at both the national and international level.

[1] This Manifesto was submitted to the discussions of the High Level Group on Chemical in September 2008

European Chemical Industry Council – Cefic aisbl
Avenue E. van Nieuwenhuyse 4 B - 1160 Brussels Belgium Tel: +32 2 676 72 11 Fax: +32 2 676 73 01 mail@cefic.be www.cefic.org

A. PATENTS

Patents are an incentive for innovation, investment and research. Not only does the availability of patent protection enables inventors to innovate and recoup expensive research costs, but, also it encourages investment in further research and development. This is particularly true in the chemical industry which is heavily dependant on patents in certain of its sectors.

The European chemical industry believes that enhancing a strong, comprehensive and workable system of patent legislation in Europe and indeed globally – because of the export orientation of the European industry – is needed. Therefore, as a major user of the patent system, we sees the following priorities:

A.I. Cost of patents - translations

Critical to achieving our objective is establishing a simple language regime for IP which balances the public interest with the need to avoid redundant or duplicate costs. We welcome the recent entry into force of the London Agreement which we believe can deliver real cost savings to our industry in procuring patents (It has been evaluated that the reduction of translation costs for an average European patent could be by 31% to 46% representing savings around 2,400 to 3,600 € per patent[2]). Numerous stakeholders are supporting a rapid ratification of this Agreement in all Member States. We therefore urge all Member States which have not done so already, to accede to the Agreement as soon as possible so the maximum benefit can be obtained.

Recommendation n° 1: Member States which have not yet acceded to the London Agreement should do so as soon as possible.

A.II. The Community Patent and Jurisdictional Arrangements

The Community Patent can also be of great assistance in this area provided that a simple system can be found. We recognise the enormous efforts made in so far by the Commission in attempting to reach this objective, which we believe should remain a key objective for Europe. Perhaps the best prospects of a way forward are offered by a regime in which there is a single language authentic text and high quality machine translations are available for informational purposes only.

Alongside the Community Patent a central jurisdictional framework for European patents remains an important strategic objective worthy of support. A common court system throughout Europe is in particular an absolute necessity. In a common market promoting the free movement of goods, differing court decisions in different Member States or regions is simply unacceptable. In addition litigation expenses become unbearable because of the multitude of courts a right owner has to go through to enforce his rights.

In particular and concerning the latest proposals of the EU Presidency on the future Community patent and the court structure, we think that an integrated court structure which covers both EPO and Community patents should be founded. The court should have competence for all cases with cross-border effects and employ uniform rules of procedure.

In such an integrated court structure the first instance should be comprised of local and regional divisions (as opposed to national courts) and both first and second instances should be provided with sufficiently experienced judges. At the first instance the local/regional division should be provided with one technically qualified judge even in the case of infringement claims. Such technically qualified judges should be available from an international pool of judges appointed by a panel of IP-experts from the Member States. In

[2] See page 3, 5th paragraph, footnote 10 and Annex II of the Commission Communication to the European Parliament and the Council "Enhancing the patent system", COM (2007), 29-03-07

the long term all local/regional divisions should be international and staffed by judges from across Europe. The language of first instance should in all divisions be the language in which the patent was granted although the parties should be free to agree a different regime language which would be binding on the court. An additional translation only for informational reasons should be possible at the expense of the party who has requested it.

Recommendation n° 2: ***The Commission and Member States are encouraged to actively continue their efforts to reach an agreement on the creation of a Community patent and a common jurisdictional framework within which European and Community patents can be enforced.***

A.III. Quality System for Granting Patents

The protection of high quality patents gives reliable and predictable protection to the chemical industry. The European Patent Office (EPO) and its independent Boards of Appeal contributed in searching and rigorously examining patent applications in a timely fashion.

The rapid growth in global patent filings in the last five years has however challenged the efficient working of the EPO and other major Patent Offices. Concerns have been expressed about the difficulties that EPO has in achieving its mission. We believe that this may have resulted in part from the governance arrangements of its Administrative Council that is composed of the National Patent Offices. As a consequence, we call for the "Contracting States" to consider this.

In addition, the EPO's Board of Appeal has divergences from the Member State courts (that are all the final arbiter of patent validity). This problem is likely to be exacerbated in the near future with the creation of a European patent jurisdiction having as one of its remits the revocation of the European Patent bundle in its entirety. Therefore, we encourage discussion of this issue.

Recommendation n°3: ***The "Contracting States" which are also Member States should focus on streamlining and possibly simplifying the EPO's governance arrangement. At the same time the linkage between the Boards of Appeal and the forthcoming European patent jurisdictional arrangements should be debated. In both cases there should be widespread consultation of the chemical industry and all interested parties.***

A.IV. Global Harmonisation of Patent Laws and TRIPs

Given the global nature of patent issues and by virtue of the role it plays in the World Intellectual Property Organisation (WIPO), we believe that the Commission and the Member States – in cooperation with other key stakeholders - can be very influential in harmonising laws and continuing to support strong IP regimes in other countries and areas where IP challenges persist, including Russia, Latin America, the Middle East, and Asia (except Japan). Not only do we see these as desirable ends in themselves, we believe that they are key to resolving some of the workload pressures that Patent Offices face and promoting world trade. However, in pursuing the objective of patent law harmonisation we recognise the scale of the political challenges involved in balancing both European "first-to-file" and US "first-to-invent" legal traditions and the expectations of the first and third worlds. For this reason we favour a process which seeks incremental improvements based on the best or most widely used practices and what we create must be better than what we have now for the exercise to be worthwhile.

The development of a globally reliable patent system is also included on the TABD – TEC agenda, which, in its 2008 EU-US Summit declaration, stated that the United States Patent and Trademark Office and the European Commission have agreed to a roadmap to advance global patent harmonization.

We believe that key to all of this is a strong and influential WIPO overseeing the Patents Cooperation Treaty (PCT) as the entry portal to the world patent system[3]. We believe that the Commission and Member States should actively support the PCT as the world standard and resist alternative bilateral initiatives which, although possibly delivering short term benefits dilute its role and remove coherency from the system.

Recommendation n° 4: The Commission and the Member States should pursue patent law harmonization in the WIPO and TABD-TEC so as to produce benefits for the chemical industry. The Commission and Members State should actively support the Patents Cooperation Treaty and seek to resist bilateral arrangements which dilute its role.

B. CONFIDENTIAL BUSINESS INFORMATION (CBI) / DATA PROTECTION

Like any other IP right, data protection plays an important role for the chemical industry. So far, when considering the relationship between IP and innovation much attention was given to patents, but, protection of CBI which is also part of the valuable assets of companies has been less prominent. However, the effective management and exploitation of CBI is equally important for chemical companies in Europe. This is particularly true for SMEs who may not have the resources to create and maintain a portfolio of registered IPR on the one hand and have little experience of managing trade secrets on the other. Moreover there are instances into which unregistered IPR are the only solution available.

In the area of CBI we believe that a single approach to the handling of business secrets made available to the various EU regulatory bodies is needed. A single balanced approach in line with the objectives of Article 39 TRIPS Agreement[4] on the protection of undisclosed information would we believe enable everyone to understand their roles and responsibilities in this area. It should be recognised that in the chemical industry some of the most valuable IP exists in the form of unpublished know-how not susceptible to protection by patents.

In general terms, since this right is not granted by an authority (contrary to other IPRs such as patents and trademarks), it causes considerable difficulties for industries that always firstly

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[3] This Treaty makes it possible to seek protection for an invention simultaneously in each of the country -as designated by the applicant- having acceded to the Treaty (currently139), by filing an "international" patent application. This application may be filed at one of the national patent office or WIPO. This application is then subject to an "international search" to be carried out by one of the patent offices appointed by the PCT bodies for this.

[4] Abstracts of Article 39 WTO- TRIPs Agreement (Trade Related Aspects of IPRs) :

1. *……Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.*

2. *Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:*
(a) *is secret in the sense that is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;*
(b) *has commercial value because it is secret; and*
(c) *has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.*

3. *Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.*

have to demonstrate the existence of the right when engaging in negotiation on new pieces of legislation or at the occasion of their application either by EU or national authorities. The general lack of knowledge of the existence of this IPR forces industry into a defensive position in view of private and public demands for placing all information in the public domain without paying attention to the legitimate right of the owner of CBI. More particularly the following problems have to be pointed out:

- Piecemeal approach into sectoral legislation;

- Lack of translation of Article 39 of the TRIPs (Trade Related Aspects of Intellectual Property Rights) Agreement at EU level in general terms;

- Constant erosion of this IPR as being a weak element of the legitimate rights of companies in view of the increasing demands for "total transparency";

- Illustration from the European Court of Justice case law[5] that the principles are to be recognised and this IPR to be taken out seriously by the Institutions. But, why does company have to go into litigation to have their legitimate IPR preserved at EU level?

  The ABNA case concerns an EU Directive[6] which – at the summit of the BSE crisis – aimed to introduce an obligation to disclose formulas of feedingstuff, by declaring the exact quantity of ingredients used at a customer request. The claimants, manufacturers of feedingstuff for animals, contested this basing their arguments on the infringement of a fundamental right to property and of the principle of proportionality.

  The Court decided that *"the right of property… forms part of general principles of Community law. However, those principles are not absolute but must be viewed in relation to their social function. Consequently, the exercise of the right to property …may be restricted, provided restrictions in fact correspond to objectives of general interest pursued by the Community and do not constitute in relation to the aim pursued a disproportionate and intolerable interference, impairing the very substance of the rights guaranteed."* (point 87). Looking into the particular question at stake, the Court held that the obligation for manufacturers to indicate the exact composition of a feedingstuff at a customer's demand was infringing the proportionality principle as this could not be justified *'by the objective of protecting public health which is pursued and manifestly goes beyond what is necessary to attaint that objective"* (point 83).

  The Court further indicated that the passing on relevant data to the authorities (under strict confidentiality) was enough to fulfil the aim of the Directive *"it must be point out that Article …. Provides that manufacturers of compound feedingstuff are obliged to make available to the authorities responsible for carrying out inspections, on request, any document concerning the composition of feedingstuff ….which enables the accuracy of the information given by the labelling to be verified"* (point 84).

  5 companies supported by Cefic have lodged another series of cases in the ECJ, because they consider that certain implementing rules adopted by the Commission in the framework of Directive 98/8/EC on biocides among others infringe the intellectual property rights of companies having submitted data for the purposes of the Directive by

[5] See for example the ABNA Case – ABNA V/s Secretary of State for Health and others, C-453/03, judgment form 6 December 2005.
[6] Directive 2002/2 of 28 January 2002 amending Council Directive 79/373/EEC on the circulation of compound feedingstuff (OJ L 63, 06 03 2002, p 23).

allowing "free riding" of other companies[7]. The ECJ has not yet decided on these cases, but did reject requests from industry for suspending the effects of the contested Commission Regulations while the cases are being heard.

- Other international organisations are working on this issue in more general terms – why not the Commission?

  For many years the OECD has worked on this issue and is pursuing its reflection on this. Already in 1983 the OECD Council adopted three Resolutions[8] setting out in general terms the principles underlining such IPR and recognising in broad terms *"the economic value of certain data on chemicals, in particular health, safety and environmental data, and the possible adverse effect of the disclosure of these data on the competitive position of the person or company who developed the data"*.

In general terms, the proportionality principle requires that any exception must be appropriate and necessary to realise the objectives defined, must not constitute an excessive restraint on companies' rights and must not affect the very substance of those rights[9].

It is therefore imperative that the disclosure regime in Europe allows companies to properly raise their objections and concerns and those to be effectively considered by due process of law otherwise EU industry risks being disadvantaged relative to other trading blocks. The chemical industry sees that the Commission can play a pivotal role into this in facilitating such a process.

Recommendation n°5: The Commission and the Member States should further recognise that confidentiality is an important IPR and ensure that the proportionality principle is applied systematically, when striking the balance between the legitimate protection of confidential business information and other policies such as transparency and access to documents.

Awareness of this IPR should be emphasised by relevant industry associations in their information activities to members and by the Commission and Member States when developing innovation policies relevant to SMEs.

C. COUNTERFEITING

Counterfeiting is not simply a problem of the luxury branded goods market. Increasingly it is a crime which pervades all areas of business life. Many of the products we provide are manufactured in plants meeting high environmental standards and the products themselves are subject to stringent health and safety assessments. Low quality counterfeits risk compromising this to the detriment of consumer expectations and even health. They also affect public confidence in science and undermine the reputation of our industry.

We have concrete examples in our sector of widespread counterfeited active pharmaceuticals ingredients being "sub-standard and unsafe" substances that were imported from China and India and used to produce medicines, which caused recent serious incidents (eg heparin imported from China that was contaminated with "oversulfated chondroitin sulphate"). This problem occurs at large scale since over 80% of the active pharmaceuticals ingredients used in off-patent medicines are sourced from these countries. Many other

[7] Case T-120/08.
[8] OECD 1983 Recommendations of the Council concerning the (i) Protection of proprietary rights to data submitted in notifications of new chemicals (ii) Exchange of confidential data on chemicals (iii) List of OECD non-confidential data on chemicals.
[9] Case C-265/87, Schräder, ECR [1989], I-237, point 15.

sectors of the chemical industry are hit by counterfeiting such as: the pesticides, fibres (eg counterfeited material used to produce fishing nets or “bullet proof” helmets).

Therefore, we support the Commission’s strong co-ordinated action in Europe against counterfeiters wherever they may be and whatever they may counterfeit. In this respect we are very supportive of the recently introduced IP enforcement Directive which we hope will be a major tool in the fight. We also support educational initiatives designed to raise consumer awareness of the issue in Europe and the EU taking a strong position on this in trade discussions with other countries. Counterfeit chemicals from East Asia especially China are becoming an increasing problem to the chemical industry in Europe and enforcement is a general challenge.

Recommendation n° 6: The Commission and all players involved in the fight against counterfeiting and piracy in the Member States including European industry should continue to facilitate and conduct strong enforcement actions against counterfeiters in Europe and elsewhere in the world, to seek leadership on a co-ordinated approach to this issue and develop public educational initiatives.

D. TECHNOLOGY TRANSFER

The European chemical industry is supportive of activities which raise the public’s awareness of the importance of IP and which enhance innovators’ understanding as to how to obtain benefit from their ideas. In this respect we are in favour of initiatives such as the European Patent Academy, the European Institute of Innovation and Technology (EIT) and equivalent activities being undertaken in the EU Member States. We also recognise the work that the Commission has put into improving the IP regime around Framework 7 proposals.

The chemical industry also supports in this context the recently adopted Commission Recommendations on the management of intellectual property in knowledge transfer activities and code of practices for universities and other public research organisations. However in implementing these recommendations it needs to be recognised that the issues of high investment costs, chemistry-specific market structures, and product life cycles frequently mean that chemical companies need at least limited exclusive access to many new technologies.

Recommendation n° 7: The Commission should pursue its actions to boost technology transfer in Europe and investigate solutions to provide support (both educational and operational) to smaller chemical companies, universities and single innovators in a way which is consistent with Europe’s agenda for innovation.

E. INTELLECTUAL PROPERTY WITHIN THE COMMISSION

We believe that the current fragmented approach to dealing with IP in the Commission may give the wrong impression that the EU lacks a coherent and clearly articulated strategy in this area, even if the inter-sectoral consultation is taking place. At the moment the piecemeal way IP is dealt with by the various Directorates Generals (Internal Market, Research, Trade, Enterprise, etc), each having their own specialised interests and agenda makes it difficult for both industry and stakeholders to interface efficiently with policy makers. Therefore, we advocated in favour of a more centralized co-ordinated approach to be created within the Commission.

Indeed, we are also often confronted with a confusing maze of overlapping responsibilities or having no interlocutor at all.

One good example for this is CBI. We wrote in our Comments addressed to the Commission in November 2006 the following:

"Difficulty to find an interlocutor at Commission level - this IPR is totally underdeveloped at EU level

So far, the legal protection of IPRs has been addressed mainly by DG Internal Market, implying that it will act only if there is a problem of internal market and harmonisation to be solved. We appreciate that Cefic's comments on this issue are included in the Commission Staff Working Document published on 20 September 2006[10] in view of the hearing to be held on 29 November 2006. We also consider that DG Trade should also involve in IPRs, as there be a trade related question, DG Research regarding innovation, and DG Enterprise & Industry to try to find practical solution.

Industry is finding it very difficult to identify the "relevant" interlocutor to discuss our general demand, no one seems to be readily identified and available to take responsibility for it. Contrary to other trade blocks such as the USA and Japan, it does not appear yet that there is a DG addressing IPR taking into account the needs of industry. "

In the present case, this IPR is dealt with by the General Secretariat on a more inter-sectoral and horizontal way in the context of the revision of Regulation 1049/2001, but, only in this context.

We believe that this dispersion of responsibilities about IPR which appear to be treated on a case by case basis do not allow (or at least help) the development of a strong IPR EU policy.

Central co-ordination and even a specific structure are needed to progress in the field of IPR and innovation in the EU and, in instance such as when making the interface with DG competition to engage into discussions on where to strike the balance between IPR and EC competition law.

> ***Recommendation n° 8: The Commission to enhance the dealing of IPR within its own services and DGs with a centralised co-ordination and adequate structure.***

Contact :
Nicole L Maréchal
Cefic Senior Legal Counsellor & Governance Officer
nma@cefic.be tel : ++ 32 2 676 72 18

[10] Public consultation on a future single market policy – Summary of responses – SEC (2006) 1215.