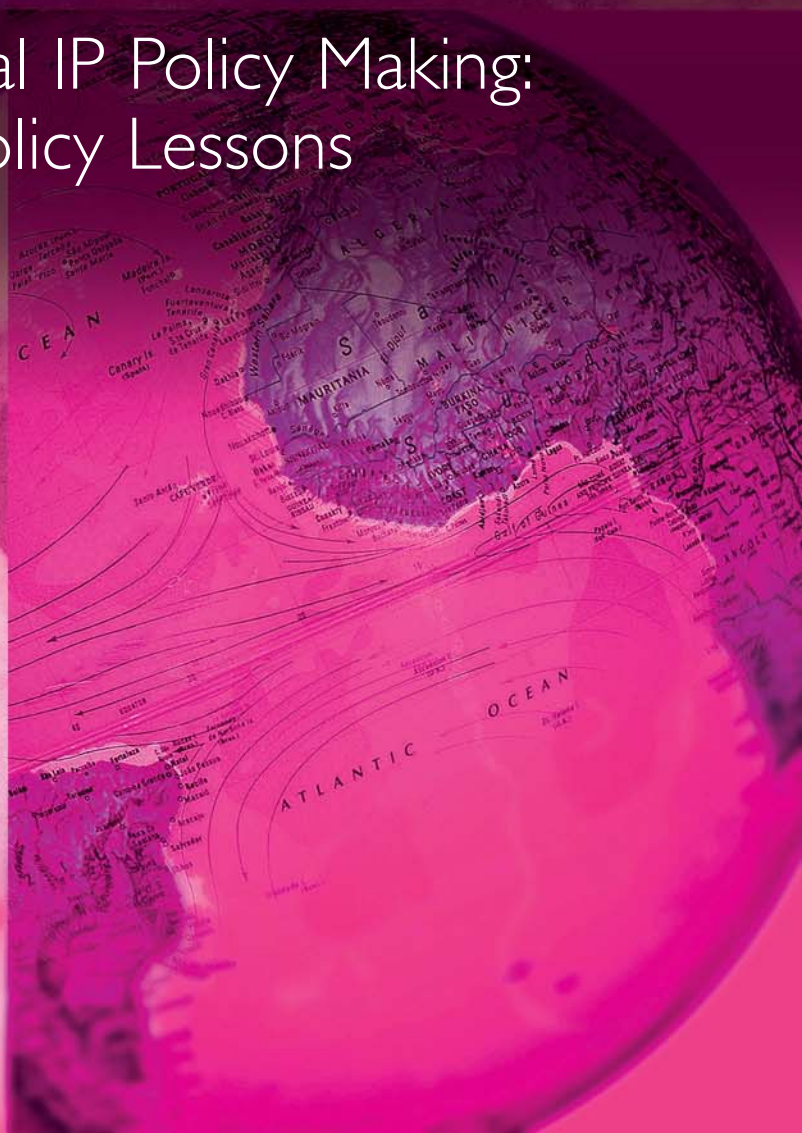




## The Stockholm Network Experts' Series on Intellectual Property and Competition

The Process of National IP Policy Making:  
Theory, Practice and Policy Lessons



by Michael Blakeney

# The Process of National IP Policy Making -

## Theory, Practice and Policy Lessons

By Michael Blakeney

Director, Queen Mary Intellectual Property Research Institute

Queen Mary, University of London

## Table of Contents

1.	The Universal Applications of IP	page 3
2	International IP Policy	page 4
3	National IP Policy, e.g. UK	page 5
3.1	UK Patent Office	page 5
3.1.1	General Policy Mandate	page 5
3.1.2	Intellectual Property Advisory Committee (IPAC)	page 5
3.1.3	Review of Inventive Step Requirement in UK Patent Law	page 7
3.2	Treasury - Gowers Review 2006	page 7
3.2.1	Launch of the review	page 7
3.2.2	Scope of the review	page 8
3.2.3	Issues paper	page 9
3.2.3.1	How IP is awarded	page 9
3.2.3.2	How IP is used	page 9
3.2.3.3	How IP is licensed and exchanged	page 10
3.2.3.4	How IP is challenged and enforced	page 10
3.2.3.5	Critique of the Review	page 12
3.3	Department for International Development - Commission on Intellectual Property Rights	page 13
3.3.1	Terms of Reference	page 13
3.3.2	The Commissioners	page 13
3.3.3	The work of the Commission	page 14
3.4	IP Policy in the Health Sector	page 14
3.5	Other UK Government IP Policy Initiatives	page 15
4	IP Policy Formulation in the EU	page 15
4.1	DG Internal Market and Services	page 15
4.2	DG Trade	page 16
4.3	DG Enterprise	page 17
4.4	DG Research	page 18
4.5	DG Information Society and Media	page 18
4.6	DG Taxation and Customs Union	page 19
4.7	DG Enlargement	page 19
4.8	Other EU Institutions	page 19
5	Conclusion	page 20
	Annex I	pages 21-27

## **Executive Summary\***

IP has applications across many different human activities: industry, commerce, health, nutrition, communications and culture. This is reflected first in the large number of national, international and regional treaties, conventions and laws which have an IP application, as well as in the large number of national, international and regional organisations and government departments asserting an IP policy-making role. A result of this crowded policy field is that IP policies are sometimes overlapping, contradictory and confusing. It is also difficult for countries to participate effectively in the many different policy fora. This situation recommends the establishment of a capacity at the national level for inter-ministerial collaboration in IP policy formulation. In the UK an attempt has been made to invest the Patent Office, which operates within the Ministry of Trade and Industry, with an IP policy co-ordination role. This has not been very successful as the Treasury has recently taken upon itself a national policy review of IP. Also the Patent Office has had some difficulty in securing policy expertise from outside the Trade and Industry context. The health sector in the UK has been quite advanced in IP policy formulation. Following a Treasury review of the competitiveness of Public Sector Research Establishments in 1999, the National Health Service launched a comprehensive IP policy, which has been implemented by the various medical trusts which operate the public hospitals system.

### **I. The Universal Applications of IP**

It is a trite observation that IP has applications in all aspects of human existence. For example, Article 7 of the TRIPS Agreement, in defining the objectives of that instrument, declares that “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology”. Article 8 refers to “measures necessary to protect public health and nutrition”. Indeed the five most controversial aspects of the TRIPS Agreement concern the impacts of IP upon (i) the availability of HIV-AIDS drugs; (ii) food security as a consequence of the obligation of states to protect plant varieties; (iii) food security as a consequence of the patentability of genetic material; (iv) the digital divide; and (v) cultural integrity.

Other controversial aspects of the TRIPS Agreement concern the subjects which it does not cover, including: access to genetic resources; benefit sharing in relation to those resources; the protection of traditional knowledge and traditional cultural expressions.

The diversity of these subjects means that IP policy formulation has to draw upon a multiplicity of expertise in addition to IP law. An obvious challenge is to co-ordinate these expertise on a national basis and between national and international organisations and agencies.

\* This paper is based on a presentation held at the Stockholm Network- MSD IP Academy in Israel on June 22<sup>nd</sup> 2006

## 2. International IP Policy

A consequence of the broad impacts of IP is that a number of international and trans-national organisations and agencies are concerning themselves with this subject. Listed below are the principal international organisations which have IP as a concern. Also indicated are the national government ministries which typically liaise with those organisations.

Organisation	Location	Topics of Concern	Corresponding national ministries
World Intellectual Property Organization (WIPO)	Geneva, New York, Singapore	All IP	Industry, Science, Culture, Communications
World Trade Organization (WTO)	Geneva	All IP	Trade, Foreign Relations
World Health Organization (WHO)	Geneva	Patents	Health
Commission on Intellectual Property Rights Innovation and Public Health (CIPRH)	Geneva	Patents	Health
United Nations Conference on Trade and Development (UNCTAD)	Geneva	All IP	Trade, International Development
International Union for the Protection of New Varieties of Plants (UPOV)	Geneva	Plant Varieties	Agriculture
Food and Agricultural Organization (FAO)	Rome	Plant varieties and patents	Agriculture
Conference of Parties (COP) of the Convention on Biological Diversity (CBD)	Nairobi	Plant varieties and patents	Agriculture, Environment
United Nations Environment Programme (UNEP)	Gland	Plant varieties and patents	Environment
United Nations Economic, Scientific and Cultural Organization (UNESCO)	Paris	Copyright	Culture
United Nations Industrial Development Organization (UNIDO)	Vienna	Industrial Property	Industry
Consulting Group on International Agricultural Research (CGIAR)	16 locations	Plant varieties and patents	Agriculture
International Police Organization (Interpol)	Lyon	Enforcement of all IP	Police, Justice
World Customs Organization (WCO)	Brussels	Enforcement of all IP	Customs, Revenue, Justice

An obvious consequence of the involvement of so many international organisations in the formulation of IP policy is the difficulty of securing a consistent approach in relation to common subjects. The diversity of organisations in different locations lends itself to this inconsistency. For example, at the same time (November 2001) that the WTO was engaged in the Doha Trade Ministers' meeting, the FAO, together with CGIAR, was formulating a Treaty on Access to Genetic Resources for Food and Agriculture, the COP and UNEP were examining modalities governing access to genetic resources and benefit-sharing and WIPO was examining the same subject in the context of the negotiation of its Substantive Patent Law Treaty. The same topic was also being examined by UNCTAD and its International Centre for Trade and Sustainable Development (ICTSD). Since the country representatives at these meetings are selected from different ministries, with different cultures, it is not surprising that different policy approaches have emerged. For example, the WTO representatives come from foreign relations, economics and trade backgrounds, the FAO, CGIAR and UNEP representatives come from various scientific backgrounds. WIPO representatives generally come from patent offices or industry ministries. UNCTAD representatives generally come from economics backgrounds. Sprinkled amongst these representatives will be lawyers with a lesser or greater

understanding of IP. Providing country representatives for all of these fora concerned with IP is a challenge for all countries. Invariably, for poorer countries which are distant from the places where the negotiations are occurring, the national representation may be undertaken by the local diplomatic representative.

### **3. National IP Policy, e.g. UK**

The difficulty of securing consistency in IP policy formulation at the international level is exacerbated by the difficulty of securing consistency in IP policy formulation at the national level. An illustration of these difficulties is provided by the UK. In the UK a number of Ministries and agencies have concerned themselves with IP policy. Additionally, the UK as an EU member is subject to the direction of the various Directorates General of the European Commission which have also assumed an IP policy role.

#### **3.1 UK Patent Office**

##### **3.1.1 General Policy Mandate**

The website of the UK Patent Office<sup>1</sup> declares that:

The Patent Office is responsible for developing and carrying out UK policy on all aspects of intellectual property. The Intellectual Property & Innovation Directorate (IPID) deals with the policy for patents, copyright (and related rights), trade marks, designs and geographical indications of origin, and co-ordinates on issues affecting both copyright and industrial property matters.

The Patent Office is an agency of the Ministry for Trade and Industry (DTI). The DTI's website confirms that the Patent Office is responsible for

The Patent Office website claims that it has a "close working relationship" with the DTI and that it "consults within government as necessary before formulating policy advice to DTI Ministers."

##### **3.1.2 Intellectual Property Advisory Committee (IPAC)**

Cognisant of the fact that Patent Office officials, who typically come from science or engineering backgrounds, cannot possibly represent the diversity of interests embraced by IP, the Office has established an Intellectual Property Advisory Committee (IPAC) as a "body formed to give high level independent advice to Government on intellectual property issues." IPAC is currently chaired by the chief executive of a corporation which was set up to assist universities in the exploitation of their IP.<sup>2</sup>

The Terms of Reference of IPAC are to consider:

- how to foster the development of an international and European IPR system which encourages innovation and competition and promotes global trade, for the benefit of commerce, industry and consumers;
- how best the intellectual property system can meet the needs of SMEs as well as large businesses, and maintain a balance between the interests of rights owners and users;
- the wider economic impacts of IP policy;
- the interface between IP protection and competition policy;
- how new technology affects IPRs and how the IPR system needs to be adapted as a result;
- issues of potential public concern about the appropriateness of IP protection in areas such as biotechnology;
- the need for consultation about emerging issues and how this should be framed and targeted;
- areas which would repay possible further research;

---

<sup>1</sup> <http://www.patent.gov.uk>.

<sup>2</sup> British Technology Group plc.

- the findings and recommendations of other Government advisory bodies which consider IP issues.

The Patent Office undertakes to take account of any recommendations from the committee “when advising Ministers, when such advice relates to areas in which the committee has taken an interest and offered views.” The Patent Office also undertakes to “consult as necessary with interests on recommendations which the committee makes.”

The first impression that one has is that the IPAC is a useful corrective to the potential technocratic narrowness of the Patent Office as an IP policy formulator. However, a review of the activities of IPAC identified a number of inadequacies in its contribution to policy formulation. This review was inaugurated in October 2004 in line with Cabinet Office guidance for reviewing small, advisory non-departmental public bodies. The aim of the review was to ensure “that ministers and officials receive and are able to act upon timely and expert advice relating to strategic issues that will affect the handling and exploitation of intellectual property in the future; so that UK, European and international systems for managing intellectual property boost innovation and competition and drive up UK productivity and competitiveness.”

The intended outputs of the review were:

- An evaluation of the performance of IPAC in the context of the committee's original terms of reference.
- An assessment of whether IPAC's current remit addresses the needs of ministers and officials for advice on the strategic issues affecting intellectual property.
- An assessment of whether IPAC, as currently constituted, is the most effective and efficient way of addressing this need.
- Subject to this assessment, recommendations relating to enhancing the performance of IPAC to meet the needs of ministers and officials, including:
  - possible revision of IPAC's terms of reference;
  - changes to its ways of working;
  - resources available to IPAC; and
  - the secretariat support the committee receives.

Among the conclusions reached in the review were that

“overall, IPAC has not adequately fulfilled its role and has largely disappointed the expectations of both its members and other stakeholders. It has not produced enough substantive output. Its investigations into some issues have been too protracted. It has operated with insufficiently robust or clear business processes. The reasons for this are broadly:

- i. lack of clarity about IPAC's role: IPAC members are uncertain about what is expected from them; and there has not been any significant appreciation in Government departments about how IPAC might help them, thereby suppressing demand for IPAC's services;
- ii. lack of resources: IPAC has struggled to perform its role without a full time secretariat, no administrative budget to resource its operations or programme budget to commission research or other consultancy support;
- iii. group dynamic: the committee, as a group of experts, could have functioned better if the issues of IPAC's role and resources (points i and ii above) had been fully addressed. This would have allowed members to forge a stronger sense of community.”

As a consequence, IPAC's contribution to and impact upon policy making, as envisaged in the committee's terms of reference, was perceived to have been limited. However, consultation with a range of stakeholders indicated “unanimity over the need for independent, expert and strategic input to policy making in intellectual property. Intellectual property is regarded as too important a policy agenda not to have this capability available to policy makers in Government.”

The review's provisional recommendation was that DTI / Patent Office should continue to operate an advisory body to contribute expert and independent views on intellectual property. It recommended 're-launching' the advisory body, the review referred to the necessity of:

- i. bringing IPAC's role into sharper focus: clarifying its function and building a consensus around this purpose; creating demand in Government for IPAC's services; and connecting the committee's deliberations on strategic issues more effectively with the hot policy issues facing departments that are affected by or have bearing on intellectual property; while maintaining the IPAC's independence.
- ii. re-invigorating the committee itself: addressing the size and composition of IPAC to ensure it brings together a well rounded and comprehensive set of viewpoints in intellectual property; and structuring meetings of IPAC more effectively to deliver real value to members, Government and other stakeholders.
- iii. investing more resources in the operation of IPAC to enable it to succeed: in particular, introducing a full time secretariat dedicated to servicing the needs of the committee, project managing its work programme and helping to raise awareness of IPAC in Government and with other stakeholders.
- iv. introducing more robust ways of working: for how IPAC defines, implements and evaluates its programme of work; and which interconnects and creates synergies between the work programme and the policy agenda of the Patent Office and other stakeholders in Government.

### **3.1.3 Review of Inventive Step Requirement in UK Patent Law**

At the beginning of 2006, the Patent Office announced a "review to re-evaluate the inventive step requirement and its influence at all levels."<sup>3</sup> The review was considered timely to because not only had considerable time elapsed from the passage of the 1977 Patents Act, which introduced this requirement, "but also because more recently it has been the subject of some debate and investigation abroad: these have raised serious issues of patent quality, and concerns over the issue of so-called "trivial" patents."

The objectives of this review are:

- to gather information as to the inventive step requirement in the UK, and how it compares with other countries;
- to assess whether the level for inventive step in the UK is set at an appropriate point having regard to the underlying objectives of the legislation, to the role of the patents system in the economy of the country, to the knock-on effects on third-parties, to consistency and harmonisation with other countries, and to quality generally;
- if any aspect should be modified, to set out proposals.

A questionnaire has been prepared in which "evidence will be sought: from users of the patent system and other interested stakeholders." Responses are sought by 31 May 2006. As will be seen below this review is exactly contemporaneous with a review of the UK IP system commissioned by the Chancellor of the Exchequer. The evidence which is sought is very similar to the information on patents being sought in the Treasury Review.

A questionnaire has been prepared in which "evidence will be sought: from users of the patent system and other interested stakeholders." Responses are sought by 31 May 2006. As will be seen below this review is exactly contemporaneous with a review of the UK IP system commissioned by the Chancellor of the Exchequer. The evidence which is sought is very similar to the information on patents being sought in the Treasury Review.

## **3.2 Treasury - Gowers Review 2006**

### **3.2.1 Launch of the review**

Given the amount of experience of the Patent Office in IP policy formulation and the effort which has been devoted to sorting out the advisory role of IPAC, it came as something of a surprise when the Chancellor of the Exchequer announced at the end of 2005, the appointment of Mr Andrew Gowers to conduct a review of IP in the UK. According to the *Wikipedia* "Andrew Gowers was appointed editor of the Financial Times in October 2001. He left

---

3 See Patent Office Website.

this post in November 2005 due to disagreements over strategy with the Financial Times' owner, Pearson.” His cv is almost exclusively devoted to a career in journalism, although he wrote a biography of Yasser Arafat in 1990. There is no evidence of any previous involvement with IP or IP policy.

On 23 February 2006 Mr Gowers wrote to “key contacts across a range of industry sectors, including scientific, high-tech, manufacturing, media and creative industries, as well as public sector and third sector bodies, relevant industry associations, inventors’ bodies, consumer groups, experts in corporate finance and venture capital, the legal profession, and leading economists and other academics in the field.” to submit “evidence” to the Review team. The letter indicated a submission date of 21 April 2006 and that the Review would report to the Chancellor, the Secretary of State for Trade and Industry and the Secretary of State for Culture, Media and Sport in autumn 2006, “with targeted and practical policy recommendations as appropriate.” The letter was accompanied by an issues paper.

This paper observed that “while it has been suggested that the present UK system strikes broadly the right balance between consumers and rights-holders, it also appears that there are a variety of practical issues with the existing framework.” These were:

- complexity of the system;
- “significant costs for businesses and innovators” in securing protection, as well as the costs of enforcing IP and challenging infringement through litigation;
- impediments to the development of the next generation of products and associated competition through the granting of over-broad patents;
- the increasing complexity of high-tech products requiring firms to use large numbers of existing patents to develop new products, sometimes necessitating the negotiation of complex licensing agreements, often with multiple rights-holders holding overlapping patents;
- the increase of barriers to market entry through cross-licensing agreements and “patent pools”;
- the lack of clarity in copyright exceptions and infringement sanctions in dealing with impact of the Internet and high-speed digital networks upon the development of widespread copyright infringement, most notably through the use of file sharing.
- the barriers to efficient markets for copyright licensing in relation to unavailable copyrighted works. are presently unavailable

The issues paper indicated that in many cases the Review’s recommendations would focus on how the Government might address these issues domestically. However, because of the international environment within which IP policy is formulated, the issues paper foreshadowed that “the review might make policy recommendations at the international level, considering how best the Government can continue to take a lead internationally. It will bear in mind the need to balance the Government’s aims of promoting innovation, openness to trade and investment, and international development concerns. It will also consider how best to influence the European Commission’s agenda on intellectual property policy in the EU, including its review of legislation on copyright and related rights.”

### **3.2.2 Scope of the review**

The scope of the review was identified as examining all elements of the IP system, to ensure that it delivers incentives while minimising inefficiency. Specifically:

- The way in which Government administers the awarding of IP and provides support to consumers and business. The award and observance of IP should be predictable, and transparent, with minimal information costs and transaction costs for firms and citizens.
- The way in which businesses and other organisations use IP. The structure of the IP framework should reflect the impact of economic and technological change on the nature of intellectual assets and their importance to businesses across different sectors.
- How well businesses, other organisations and individuals are able to exchange and trade IP – in particular negotiating the complexity and expense of the copyright and patent systems, including copyright and patent licensing arrangements. Exchange of IP should be facilitated by accurate valuation, with no barriers in access to finance, and liquid markets.

- How well businesses and others are able to challenge and enforce IP. Litigation and enforcement should be swift, efficient and judicious with the optimal mix of technical and legal measures. Businesses should be aware of the range of alternative methods to challenge and enforce IP such as mediation and alternative dispute resolution. These methods should be relatively inexpensive, swift, efficient and transparent.

### 3.2.3 Issues paper

General questions raised in the issues paper were:

#### 3.2.3.1 How IP is awarded

- (a) Are there barriers to obtaining IP rights due to system complexity? What could be done to improve this situation?
- (b) How easy is it to find out about obtaining IP rights? What could be done to improve awareness for businesses and innovators? Is there sufficient awareness of the need to protect IP internationally?
- (c) Are there barriers to obtaining UK IP rights on grounds of cost? What drives these costs?
- (d) How do these costs compare internationally in your organisation's experience?
- (e) Do you have any comments on the UK Patent Office fees structure for obtaining and renewing IP protection?
- (f) Is lack of trust in the system a barrier? To what extent do you rely on other tools to bring innovation to the marketplace, such as being first to market, maintaining trade secrets, or using an open innovation model to generate value through reputation or network effects?
- (g) Are there specific barriers to obtaining IP rights in your sector?
- (h) Are there specific barriers to obtaining IP rights for small businesses or individuals?
- (i) How well does the national system for awarding IP, administered by the Patent Office perform? How well do the international and European systems work?

#### 3.2.3.2 How IP is used

- (a) What types of IP does your organisation use and why?
- (b) To what extent do you seek multiple overlapping forms of IP protection?
- (c) To what extent are these decisions influenced by sector-specific considerations?
- (d) How does your company value its IP? Are there problems with raising finance against intangible assets based on IP? What improvements could be made in this area?
- (e) To what extent does the term of IP rights at the margin affect investment decisions?
- (f) How well does the UK IP system promote innovation?
- (g) To what extent does your organisation make use of other methods used by Government to encourage innovation, such as public funding?
- (h) Are data on the use of patents and other forms of IP useful as a means of measuring innovation?
- (i) Do you have any evidence as to the static or dynamic costs that IP rights (as statutory monopolies) impose on the economy?
- (j) Have you encountered patents or other IP rights being used defensively, i.e. obtained not to develop products, but only to prevent others from doing so? Under what circumstances do you consider this acceptable?

### **3.2.3.3 How IP is licensed and exchanged**

- (a) How easy is it to negotiate licences to use others' IP for commercial or non-profit purposes?
- (b) What mechanisms do you use for finding potential licensing partners?
- (c) How easy is it to use others' IP for research purposes? Have you experienced difficulty around research exemptions?
- (d) Are there specific barriers to licensing in the main forms of IP currently used: patents, copyright, trade marks, and designs?
- (e) Are there barriers to licensing IP on grounds of cost? What drives these costs?
- (f) Are there specific barriers to licensing IP in your sector?
- (g) Does your organisation use methods to facilitate exchange of IP - such as cross-licensing or pooling IP rights with other firms or organisations?
- (h) Are there specific barriers to licensing IP rights for small businesses or individuals – for example, barriers to entry to patent pools?
- (i) Are there barriers to trade and exchange of IP internationally?
- (j) Does your organisation consider renewing patents using “licence of right” provisions in patent law (which entitle any person to a licence under your patent and reduce your renewal fees by half)?
- (k) What could be done to improve “licence of right” provisions and business awareness of them?
- (l) Do you have any experience of the compulsory licence provisions within current patent law? Are they effective? How could they be improved?

### **3.2.3.4 How IP is challenged and enforced**

- (a) Are there specific problems with enforcing the main different forms of IP: patents, copyright, trade marks, and designs?
- (b) Are there barriers to challenging infringement and enforcing your IP rights on grounds of cost? What drives these costs?
- (c) To what extent does your organisation make use of other methods than litigation to resolve IP infringement cases, for example the Patent Office opinion service, mediation services, Alternative Dispute Resolution, or the Copyright Tribunal?
- (d) To what extent do you use IP litigation insurance? How effective is it?
- (e) Are there barriers to using such methods to settle IP disputes without recourse to litigation? How might they be removed?
- (f) Are there specific barriers to challenging and enforcement of IP rights for small businesses or individuals?
- (g) To what extent is the risk of litigation a factor in your organisation's investment in innovation?
- (h) What are the principal barriers to efficient and successful challenge and enforcement internationally?

A number of specific issues were also raised in the issues paper:

➤ **Current term of protection on sound recordings and performers' rights**

The issues paper indicated that the review would fulfill the Government's commitment to examine whether the current 50 year term of protection on sound recordings and performers' rights in sound recordings was appropriate, in the light of its extension to 95 years in a number of other jurisdictions.

➤ **Copyright exceptions - fair use / fair dealing**

The issues paper indicated that views would be sought on the current exceptions in copyright law, particularly their clarity and adequacy in relation to technological change? For example, copyright law in the UK does not currently have a private "fair use" exception. Such an exception might allow individuals to copy music CDs onto their PC and MP3 player for their personal use. Consequently, the review will address whether UK law should include a statutory exception for "fair use"; how content owners would be compensated for such use; to what extent has technological change presented difficulties in use of copyrighted material in the field of education; and whether there are issues concerning the archiving of material covered by copyright?

➤ **Copyright – digital rights management**

Should digital rights management (DRM) technologies that can enable rights-holders to track usage and prevent unlicensed copying by technological means take account of exceptions to copyright, the ultimate expiry of copyright term, or the future evolution of technology.

➤ **Copyright – orphan works**

➤ **Copyright - licensing of public performances**

Whether the system of licensing and paying royalties to collecting societies for public performance of music and/or sound recordings could be clarified or simplified.

➤ **Patents – utility models**

Whether there should be a second tier patent system for simple inventions, usually subject to less examination and shorter terms than standard patents.

➤ **Pharmaceutical Supplementary Protection Certificates (SPCs)**

The extent of their use. How fair and effective are they in delivering an incentive for investment. Whether they could be improved. Whether the term of SPCs be more flexible - perhaps relating straightforwardly to the period between patent award and regulatory approval?

➤ **Trade Marks – international issues**

Could the UK trade mark system be improved to work better alongside the European system?

➤ **Designs – registered designs and unregistered design rights**

The extent to which organisations rely on registered designs and on unregistered design rights, at the European rather than national level. The role for the UK unregistered design right alongside the European design right.

➤ **Legal sanctions on IP infringement**

The adequacy in the way the law applies legal sanctions to infringement of different forms of IP or to different circumstances and whether criminal sanctions on online infringement be the same as those relating to physical infringement.

➤ **Coherence between competition policy and IP policy**

Whether competition law is effective in controlling unfair competition.

## Parallel Imports / International Exhaustion

The impact for organisations of a change in the current rules, as well as the evidence of the costs and benefits, both for consumers and firms of the current rules.

### 3.2.3.5 Critique of the Review

An obvious question about the Gowers Review is how it fits in with the existing UK IP policy arrangements, co-ordinated by the Patent Office. Obviously there is an overlap with the IP policy activities of the Patent Office. Indeed the letter of invitation inviting submissions to the Gowers Review acknowledges that “The Patent Office is currently consulting on two specific intellectual property issues: the inventive step requirement in UK patent law and practice; and the way UK trade mark applications are examined on the basis of their potential conflict with earlier trade marks.” The letter states that “While we would encourage interested parties to participate in these consultations via the Patent Office website we wish to make clear that issues related to the inventive step and the registration of Trade Marks are *not outside the scope* of the Review.”

By some alchemy which was not readily apparent, the Treasury has identified a number of “Friends of the Review”, who have been invited to contribute their views on an informal basis. A number of UK academics were asked to make such contributions and this precipitated an open letter from over 40 academics, which is reproduced below:

Dear Mr Gowers

We agree that intellectual property is crucial to the success of knowledge-based industries and that these industries are increasingly important for the UK’s economic competitiveness in the global economy.

We also agree that the intellectual property framework must balance innovation and competition. We would however stress that the public interest is a vital component in this equation.

We believe that the intellectual property system should be the subject of continuous review designed to ensure that it meets its stated ends. In this, priorities for policy development should be based upon independent multi-disciplinary evidence which takes cognisance of the economic, societal and individual values inherent in the system. We are not convinced that it will be possible for the current Review to formulate policy priorities nor gather the evidence necessary for incremental changes to the system for a number of reasons:

- The time period. It is not possible to gather, consider and submit fully reasoned evidence within the timeframe of 23 February 2006 to 21 April 2006.
- The scope of the review. IP is not only of critical value to the economy but also has impacts on other fields including health, education and cultural diversity. We question whether these can be properly investigated within the scope of the current Review.
- Expertise. We question whether it is possible for the Gowers Review Team to acquire the expertise necessary within the review period to appreciate the potential wider impact their decisions and changes may have on the system as a whole within its domestic, European and global context.
- Transparency. We welcome the open call for submissions to the Gowers Review. However we are concerned that there may be a lack of transparency. For example, It is not at clear as to why certain people have been invited to join the network of ‘Critical Friends’ and what role they are to play in this process.

Given the crucial nature of intellectual property to the knowledge based economy we believe that on-going reviews of the system should be conducted by an independent publicly funded body charged with commissioning independent research on the basis of which policy priorities can be formulated and incremental changes investigated.

### 3.3 Department for International Development (DfID) - Commission on Intellectual Property Rights (CIPR)

A significant recent event in IP policy formulation by the UK Government was the establishment of the Commission on Intellectual Property Rights, which was set up on the initiative of Clare Short, the then Secretary of State for International Development “to look at how intellectual property rights might work better for poor people and developing countries.”<sup>4</sup> The first Commission meeting was in London on the 8th-9th May 2001, and the final report was published on 12th September 2002.<sup>5</sup>

According to the final report, the idea of the Commission on Intellectual Property Rights originated in the UK Government's White Paper on International Development "[Eliminating World Poverty: Making Globalisation Work for the Poor](#)" published in December 2000 (paragraphs 142-149). The aim was "...to look at the ways that intellectual property rules need to develop in the future in order to take greater account of the interests of developing countries and poor people."<sup>6</sup>

#### 3.3.1 Terms of Reference

The Commission was asked 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, for instance in the area of traditional knowledge - and the relationship between IPR rules and regimes covering access to genetic resources.
- The broader policy framework needed to complement intellectual property regimes, including for instance controlling anti-competitive practices through competition policy and law.

#### 3.3.2 The Commissioners

According to the final report the Commissioners were “selected from a list of candidates who had agreed to have their names put forward by a selection panel consisting of senior officials from the Department for International Development (DFID), the UK Patent Office and an independent assessor.” The members of the Commission were:

<b>Professor John Barton</b>	(Commission Chair)
<b>George E. Osborne</b>	Professor of Law, Stanford University, California, USA
<b>Daniel Alexander</b>	Barrister Specialising In Intellectual Property Law, London, UK
<b>Professor Carlos Correa</b>	Director, Masters Programme on Science and Technology Policy and Management, University Of Buenos Aires, Argentina
<b>Dr Ramesh Mashelkar</b>	Director General, Indian Council of Scientific and Industrial Research and Secretary to the Department of Scientific and Industrial Research, Delhi
<b>Dr Gill Samuels</b>	Senior Director of Science Policy and Scientific Affairs (Europe) at Pfizer Inc., Sandwich, UK
<b>Dr Sandy Thomas</b>	Director of Nuffield Council on Bioethics, London, UK

---

<sup>4</sup> <http://www.iprcommission.org/home.html>

<sup>5</sup> *Integrating Intellectual Property Rights and Development Policy, Report of the Commission on*

<sup>6</sup> *Intellectual Property Rights*, [http://www.iprcommission.org/papers/word/final\\_report/](http://www.iprcommission.org/papers/word/final_report/)

### 3.3.3 The work of the Commission

The commission undertook fact-finding missions to Brazil, China, Kenya, India and South Africa to talk with key stakeholders (government, NGO, industry, academic, community, legal, etc.). The commission also consulted with developed country stakeholders in the UK, US, EU and international organisations concerned with the global IPR framework (WTO, WIPO, OECD, World Bank, UN, international NGOs etc.).

A series of key study areas were identified, which are of particular relevance to developing countries.

- the rationale for the IP system and the evidence on its impact
- the impact of intellectual property rights regimes on health; agriculture and genetic resources; traditional knowledge; and software and the internet.
- the issues in building institutional capacity in developing countries
- the effectiveness of the international system and institutions in relation to developing countries

Reports on these study areas were commissioned from international experts, assessing the current situation, important issues and existing research. A series of eight workshops were convened which brought together international experts in each of the key study areas to discuss the central issues of each topic. And in February 2002 the commission held a large international conference at the Royal Society in London to give any other interested parties the opportunity to communicate their views to the commission.

The final report of the commission containing comprehensive analysis of the evidence and policy recommendations was published on 12th September 2002 and presented at a conference which it organized in Geneva. The Commission has since been disbanded and Clare Short has departed from the front line of UK politics. However, the enduring influence of the report is probably reflected in the adoption by WIPO of a development agenda and the agitation of developing countries within the TRIPS Council to “operationalise” the development objectives of the TRIPS Agreement.

### 3.4 IP Policy in the Health Sector

In 1998 the National Health Service (NHS) adopted a Policy Framework for the management of Intellectual Property.<sup>7</sup> This was at a time when the Government had inaugurated an inquiry into the competitiveness of the public sector. In the resultant White Paper, published in December 1998<sup>8</sup> the Government announced its intention to analyse the potential of Government's Public Sector Research Establishments ("PSREs") to “make the most of the commercial potential of their research outputs.” Mr John Baker, then the CEO of Medeva, was asked to investigate the commercialisation of research in the PSREs and “to make recommendation for increasing the rate at which scientific knowledge is successfully transferred to the private sector.” In particular he was asked to investigate:

- the role of sponsor departments/Research Councils in promoting the exploitation of research in the PSREs;
- progress in improving the culture of entrepreneurship within PSREs - particularly through the adoption of new guidance on exploiting Government assets;
- the organisational capacity and expertise for managing and exploiting Government IP effectively;
- specific institutional barriers, and possible new incentives;
- spreading best practice;
- the scope for closer co-operation with the private sector.

---

<sup>7</sup> Health Service Circular (HSC) 1998/106 <http://www.innovations.nhs.uk/pdfs/106HSC.pdf>

<sup>8</sup> *White Paper on growth, competitiveness, and employment: The challenges and ways forward into the 21st century COM(93) 700 final.*

In August 1999 he published his report: *Creating Knowledge Creating Wealth*.<sup>9</sup> In relation to the management of intellectual property he was critical of the insistence of the parent body (or other Government funder) of PSREs on retaining the ownership of the IP which they generated and of its commercialisation. Responding to this concern the Department of Health has published [A Framework and Guidance on the Management of Intellectual Property in the NHS](#) which became operational under Section 5 of the Health and Social Care Act on 9 September 2002. This section included provisions allowing NHS Trusts and Primary Care Trusts to develop as innovative organisations. Subject to the approval of a business case, it empowered NHS bodies, through the Secretary of State, to take a shareholding in spin-out companies set up to exploit intellectual property. To facilitate and manage this process on behalf of NHS Trusts, a network of regional [NHS Innovation Hubs](#) was created as well as a website on Intellectual Property, NHS Innovations.<sup>10</sup>

Pursuant to this new IP policy the various public health trusts, responsible for running the public hospital system in the UK have formulated their own IP policies.<sup>11</sup>

### **3.5 Other UK Government IP Policy Initiatives**

On 2 February 2005 Culture Secretary, Tessa Jowell and Trade and Industry Secretary, Patricia Hewitt announced Government backing for a major pan-European conference on Intellectual Property “which will seek to find 21st century solutions to protect our creativity, ideas and innovation.” The Creative Economy conference on the 5–7 October 2005 brought together “industry, consumers, creators and policy makers from across Europe to explore ways of placing creativity at the heart of our economies”. And to highlight “the absolute necessity of protecting Europe's intellectual property. It was held under the auspices of the UK's EU Presidency”.

Tessa Jowell also mentioned that “last year we set up the Creative Industries Forum on Intellectual Property, a cross Government body which looks at ways of meeting the opportunities and threats that rapidly improving technology is generating.”

A Review of Government Information was carried out during the Government's Spending Review 2000 as part of the Cross-Cutting Review of the Knowledge Economy, co-chaired by Andrew Smith, the Chief Secretary to the Treasury, and Patricia Hewitt, DTI Minister for Small Businesses and e-Commerce. It was concerned particularly with the availability of information subject to Crown copyright for reproduction and reuse by the information industry.<sup>12</sup>

## **4. IP Policy Formulation in the EU**

The UK as a Member State of the EU is of course subject to the IP policy initiatives of the European Parliament and the European Commission. The European Commission is organised into 36 “Directorates-General” (DGs) and “services” (such as the Legal Service). Each DG is responsible for a particular policy area and is headed by a Director-General who is answerable to one of the commissioners. It is the DGs that actually devise and draft the Commission's legislative proposals and technical co-operation activities. A number of the Directorates General of the European Commission are concerned with the intellectual property policy formulation foremost among these are: Internal Market and Services, Trade, Enterprise, Research, Information Society, Taxation and Customs Union and DG Enlargement.

To the observer there does not seem to be much IP policy co-ordination between these DGs. This paper will summarise some of the more important policy initiatives of these DGs.

### **4.1 DG Internal Market and Services**

The Internal Market DG focuses in particular on the knowledge-based aspects of the Single Market. Its work is partly concerned with traditional instruments regulating the market, such as harmonising the laws of the Member States relating to industrial property rights to avoid barriers to trade. The aim is also to create unitary systems for the protection of such rights with Community-wide effect through the filing of one single application for protection (Community trade marks, designs and patents). The Internal Market DG is also increasingly concerned with ensuring

---

<sup>9</sup> [http://www.hm-treasury.gov.uk/Documents/Enterprise\\_and\\_Productivity/Research\\_and\\_Enterprise/ent\\_sme\\_baker.cfm](http://www.hm-treasury.gov.uk/Documents/Enterprise_and_Productivity/Research_and_Enterprise/ent_sme_baker.cfm).

<sup>10</sup> <http://www.innovations.nhs.uk/>

<sup>11</sup> See eg Appendix I.

<sup>12</sup> Cross Cutting Review of the Knowledge Economy - Review of Government Information, July 2000:

[www.hm-treasury.gov.uk/spending\\_review/spending\\_review\\_2000/associated\\_documents/](http://www.hm-treasury.gov.uk/spending_review/spending_review_2000/associated_documents/)

that the Single Market functions properly in the Information Society and the fight against Counterfeiting. A fundamental discussion on the principle of Community exhaustion of trade mark rights and its economic effects on innovation, employment and prices are also handled by the Internal Market DG, as well as the discussions on Enlargement. There has been significant intellectual property harmonisation in the EU to do away with barriers to trade and to adjust the framework to new forms of exploitation. The Internal Market DG's task is to enforce this *acquis* and to modernise and adapt it to new developments in technology or the markets concerned (eg. directive on copyright and related rights in the Information Society). It is also involved in international negotiations to improve IPR internationally.

As of November 2004 DG Internal Market and Services has the political responsibility for implementing the Lisbon Agenda to promote the European knowledge economy. In January 2005 the Commissioner announced a review of how copyright and related rights are being commercially exploited. On 16 January 2006 DG Internal Market and Trade launched a public consultation "on how future action in patent policy to create an EU-wide system of protection can best take account of stakeholders' needs". Interested stakeholders, including industry and individuals, were encouraged to reply to a questionnaire by 31 March 2006.<sup>13</sup> The feedback obtained from stakeholders formed the basis of a hearing, which the Commission organised in Brussels on 13 June 2006.

## 4.2 DG Trade

DG Trade has responsibility, among other things, for devising and monitoring internal or external intellectual property policies in accordance with the trade policies of the EU. A key policy of the EU is to secure the better recognition and enforcement of intellectual property rights. DG Trade recently announced the *EU Strategy for Enforcement of IPR in Third Countries*. The purposes of the Strategy are to:

- Provide a long-term line of action for the European Commission with the goal of achieving a significant reduction of the level of IPR violations in third countries;
- Describe, prioritise and co-ordinate the mechanisms available to the Commission services for achieving their goal;
- Inform right-holders and other entities concerned of the means and actions already available and to be implemented, and raise their awareness for the importance of their participation.

The Strategy seeks to:

- Identify priority countries: EU action will focus on the most problematic countries in terms of IPR violations. These countries will be identified according to a regular survey to be conducted by the Commission among all stakeholders.
- Awareness raising: promote initiatives to raise public awareness about the impact of counterfeiting (loss of foreign investment and technology transfer, risks to health, link with organised crime, etc.) and make available to the public and to the authorities of third countries concerned a "Guidebook on Enforcement of Intellectual Property Rights".
- Political dialogue, incentives and technical co-operation: ensuring that technical assistance provided to third countries focuses on IPR enforcement, especially in priority countries; exchanging ideas and information with other key providers of technical co-operation, like the World Intellectual Property Organisation (WIPO), the US or Japan, with the aim of avoiding duplication of efforts and sharing of best-practices.
- IPR mechanisms in multilateral (including TRIPs), bi-regional and bilateral agreements: raising enforcement concerns in the framework of these agreements more systematically; consulting trading partners with the aim of launching an initiative in the WTO TRIPs Council, sounding the alert on the growing dimension of the problem, identifying the causes and proposing solutions and strengthening IPR enforcement clauses in bilateral agreements. At the EU – Japan Summit of 2003, the Commission and Japan agreed to establish an improved dialogue in a number of areas, including IPR. An "EU - Japan Joint Initiative for IPR Enforcement in Asia" was established, focusing on elements like (i) the close follow-up of the progress of Asian countries in the field; (ii) coordinating technical assistance programmes and responsibilities; (iii) enhancing EU-Japan efforts to raise awareness in the fight against piracy and counterfeiting and to promote the strengthening of IPR enforcement; (iv) exploring the possibility to cooperate in other areas of IPR. The initiative is

---

<sup>13</sup> [http://europa.eu.int/comm/internal\\_market/indprop/patent/consultation\\_en.htm](http://europa.eu.int/comm/internal_market/indprop/patent/consultation_en.htm)

implemented by an Annual Work Plan containing specific activities. Similarly, the EC and China at the 2003 EU-China Summit agreed to hold, at least once a year, a "EU-China Dialogue on Intellectual Property". Among other issues, the discussions should focus on efforts to combat piracy and counterfeiting, institutional reforms, enforcement-related areas such as central and sub-central enforcement by customs, police, administrative and judiciary bodies, public awareness of consumers and right-holders.

- Technical Assistance- is an activity favoured by the EU for its contribution towards poverty alleviation and development. It is thus important to show that adequate IPR enforcement can contribute to this goal by making a link with investment opportunities, transfer of technology and know-how, protection of traditional knowledge, improvement of health and safety standards, etc. A flexible approach will be followed that takes into account the recipient country's different needs, level of development, membership or not of the World Trade Organisation (WTO), and main problems in terms of IPR (country of production, transit or consumption of fake goods). Cooperation programmes will only be effective if they are prioritised and indeed felt as important in the recipient country. It is also relevant to share information and to ensure a minimum level of synergy between the main providers of technical assistance, such as WIPO, the World Customs Organisation (WCO), the Member States and third countries like Japan, the US and others. The idea is to share best practices and to avoid a duplication of efforts. There are a number of EU programmes that cover IPR, such as ECAP II, for the ASEAN countries, and the recently concluded EU-China IPR programme. ECAP II comprises a regional and a national component and covers all areas of IPR. It has a value of € 5 million. An additional € 2 million is planned, to take account of the inclusion of Laos, Cambodia and Vietnam.
- Dispute settlement - sanctions: recall the possibility that right-holders have to make use of the Trade Barriers Regulation or of bilateral agreements, in cases of evidence of violations of TRIPs; in addition to the WTO dispute settlement, recall the possibility to use dispute settlement mechanisms included in bilateral agreements in case of non-compliance with the required standards of IPR protection.
- Creation of public-private partnerships. There are numerous companies and associations which have been active in the fight against piracy/counterfeiting for many years. They constitute an invaluable source of information, but also a key partner for any awareness raising initiatives.
- Supporting/participating in local IP networks established in relevant third countries; using mechanisms already put in place by Commission services (eg IPR Help Desk<sup>14</sup>) to exchange information with right-holders and associations; build on the co-operation with companies and associations that are very active in the fight against piracy/counterfeiting.
- Awareness raising: Providing better information to the public is another very relevant dimension of the Strategy. This can be divided into the following components: (i) Raising the awareness of users / consumers in third countries. This is to be done from two perspectives: (a) to promote the benefits of IPR in terms of promotion of creativity, investment, transfer of technology, protection of traditions and quality; (b) to inform about the dangers of IPR violations to public health, consumer protection, public security, etc. The Commission has made available, through its website a "Guidebook on Enforcement of Intellectual Property Rights". This Guidebook is mainly intended to assist public authorities of developing and least developed countries in their efforts to put in place systems and procedures for the effective enforcement of IPR. In particular, the guidebook considers the most common difficulties confronting those countries in the enforcement of IPR and provides guidance on how to achieve effective and long-lasting protection for such rights. The guidebook identifies useful resources which may be of assistance to authorities and right-holders facing difficulties.

### 4.3 DG Enterprise

DG Enterprise has established the IPR-Helpdesk ([www.IPR-Helpdesk.org](http://www.IPR-Helpdesk.org)). Its main objective is to assist potential and current contractors taking part in European Community funded research and technological development projects on intellectual property rights (IPR) issues. The IPR-Helpdesk advises also on Community diffusion and protection rules and other issues relating to IPR in international research projects. Another more global objective of the action is to raise awareness of the European research community on IPR issues, emphasising their European dimension.

---

<sup>14</sup> <http://www.ipr-helpdesk.org>.

#### 4.4 DG Research

DG Research identifies its mission as follows:

- to develop the European Union's policy in the field of research and technological development and thereby contribute to the international competitiveness of European industry;
- to coordinate European research activities with those carried out at the level of the Member States;
- to support the Union's policies in other fields such as environment, health, energy, regional development etc;
- to promote a better understanding of the role of science in modern societies and stimulate a public debate about research-related issues at European level.

One of the instruments used for the implementation of this policy is the multi-annual Framework Programme which helps to organise and financially support cooperation between universities, research centres and industries - including small and medium sized enterprises. One of its current commissioned research projects is investigating:

- Professor's privilege / ownership of publicly-funded research results;
- IPR provisions applicable in the Community Framework Programme;
- Prior user rights;
- Legislation applicable to technological know-how;
- IPR co-ownership provisions;
- Publishing vs. patenting;
- The experimental exception;
- the state of play and good practices regarding IPR-TT awareness/training in Higher Education Institutions; and
- Benchmarking of IP/ITT systems with the objective of identifying the most salient features of IP and technology transfer systems which are relevant to organisations involved in R&D and technology transfer

#### 4.5 DG Information Society and Media

The mission of DG Information Society is to:

- Support innovation and competitiveness in Europe through excellence in ICT research and development;
- Define and implement a regulatory environment that enables rapid development of services based on information, communication and audio-visual technologies, so fostering competition that supports investment, growth and jobs;
- Encourage the widespread availability and accessibility of ICT-based services, especially those that have the greatest impact on the quality of life of the citizen;
- Represent the European Commission in international dialogue and negotiations in these fields, and promote international cooperation in ICT research and development.<sup>15</sup>

DG Information society is concerned with the eEurope 2005 initiative, which seeks to:

- promote the development of the underlying information society infrastructure

---

<sup>15</sup> [http://ec.europa.eu/comm/dgs/information\\_society/mission/index\\_en.htm](http://ec.europa.eu/comm/dgs/information_society/mission/index_en.htm)

- stimulate the supply of advanced services, notably via the public sector ([eGovernment](#), [eHealth](#) and [eLearning](#), as well as [Digital Rights Management](#))
- promote the uptake of [eBusiness](#), building on policies such as the [.eu domain](#).

An [electronic communications regulatory framework](#) was launched in July 2003 to provide a legal framework for continuing the development of the industry, stimulating competition, creating growth and safeguarding public and user interests. The Framework covers, among other things, the management of scarce resources essential to communications. These regulatory areas are also coordinated with the [Radio Equipment and Telecommunications Terminal Equipment \(RTTE\) Directive](#). In the field of content, [European audiovisual regulation](#) aims to ensure the free provision of services and to fulfill objectives of public interest such as access to information and protection of users in areas such as commercial communication, protection of minors and human dignity.

#### 4.6 DG Taxation and Customs Union

The Customs Union is an essential element in the creation of an integrated single European market and of a common commercial policy. The role of DG Taxation and Customs Union is to maintain and defend the Customs Union and to ensure the uniform application of the nomenclature and origin rules. The Directorate General takes full part in international commercial negotiations which have an effect on the common customs policy and surveys in particular the application of the rules of origin and the preferential trading systems. A valuable source of information about the origin, the itinerary and the nature of counterfeit and pirated goods destined to, or in transit via the Community are the annual statistics released by DG TAXUD about the goods originating from third countries seized by Customs at the Community border.<sup>16</sup>

The Customs 2007 initiative of TAXUD, which will run between 1 January 2003 and 31 December 2007, will provide a legal and financial base for:

- electronic information exchange systems between national administrations,
- training seminars for customs officials and experts,
- the exchanges of officials between national administrations and
- the basis for an electronic system which will allow business to move towards a paperless customs environment.

This programme includes candidate countries for accession to the EU. Customs 2007 uses a range of instruments such as IT systems, exchanges of officials, seminars, workshops and project groups to achieve its objectives. From an EU perspective, the protection of Community interests requires good co-operation and mechanisms for the exchange of information.

#### 4.7 DG Enlargement

DG Enlargement is concerned with supervising the accession of new member states. As part of the accession process applicant states contractually undertake to comply with the European IP *acquis communautaire*. This involves: (i) the introduction of compliant IP legislation; (ii) the establishment of appropriate administrative organs; (iii) the training of government officials, judges and lawyers; and (iv) IP awareness-raising in industry and among the public. These activities have the potential for a significant impact upon the IP policies which will be pursued by new EU states.

#### 4.8 Other EU Institutions

The Office for Harmonisation in the Internal Market (OHIM) has the task of registering [Community Trade Marks](#) and [Community Designs](#). In this regard it has an indirect effect upon the EU's IP policy. Its registration policies can be questioned by the European Trade Marks and Designs Courts, which are actually national courts exercising a European jurisdiction. Of much greater significance in this regard, is the European Court of Justice, which deals with questions referred to it from the national courts.

---

<sup>16</sup> [http://europa.eu.int/comm/taxation\\_customs/customs/counterfeit\\_piracy/index\\_en.htm](http://europa.eu.int/comm/taxation_customs/customs/counterfeit_piracy/index_en.htm)

## 5. Conclusion

The multi-faceted nature of IP and its diverse applications have resulted in a multiplicity of international, national and regional entities which involve themselves in IP policy formulation. This makes consistency or effectiveness in policy formulation difficult to achieve. Co-ordination of national IP policy formulation by a body representative of the various stakeholders would seem to be a logical solution. However, as the UK experience has illustrated, where the Patent Office was identified as such a body, it has possible for powerful Government Ministers to ignore its co-ordinating role and to duplicate its policy function.

A similar picture is identified in the EU where the various Directorates General compete with each other for the IP turf.

A number of developing countries have sought to centralise IP administration, such as Indonesia (Directorate General of Intellectual Property), Thailand (Department of Intellectual Property), however, in almost all countries there is a bifurcation between copyright and industrial property offices.<sup>17</sup> An interesting microcosm of the problems which confront individual countries in the formulation of IP policies is presented by the World Intellectual Property Organization.

Its Organigram<sup>18</sup> identifies the following departments which have a role in IP policy formulation:

- Office of Legal Counsel
- Global Intellectual Property Issues
- Sector of Trademarks, Industrial Designs and Geographical Indications
- Office of Strategic Planning & Policy Development, PCT, Patents and the WIPO Worldwide Academy
- Copyright and Related Rights and Industry Relations
- Economic Development Sector
- Office of Strategic Use of Intellectual Property for Development
- Coordination Office for External Relations

Presumably this is all co-ordinated by the Director General. Each of these offices has to deal with different constituencies. The task of co-ordination is exacerbated by the overlap between the mandates of each office. The task of the Director General is also complicated by the fact that he is also the Secretary General of UPOV and one of the complex issues of contemporary intellectual property policy is the inter-relationship between patent protection and plant variety rights protection.

Another factor which will increasingly complicate the situation is the convergence between IP categories. In its grossest for this is illustrated by the convergence between industrial property and copyright in the arena of traditional knowledge.

To conclude, although developed countries have a long and rich tradition of IP policy making, the process of this formulation, especially in the last decade, has not always been efficient and, at times, has even been contradictory. Developing countries, especially those who now have the chance to enter into the IP world, have an opportunity to create a more synchronised, informative and comprehensive style of policy making, that is based on an inter-ministerial and multi-faceted coordination at the national level. And, who knows, maybe in 20 years time this coordination model may even become the common wisdom.

---

<sup>17</sup> See annex I

<sup>18</sup> <http://www.wipo.int/about-wipo/en/pdf/org-en.pdf>

# Annex I

## The North West London Hospitals NHS Trust: Policy Relating To Intellectual Property

### 1. Introduction

A framework and guidance on the management of Intellectual Property (IP) in the NHS has recently been published. This is part of the continuing development of a strategy for the exploitation of IP arising from research and development in the NHS in response to the Government White Paper on Science and Innovation (1) and the Government Response to the Baker Report (2). The powers in Section 5 of the Health and Social Care Act 2001 allow an NHS Trust, among others, to exercise the powers in Section 7 (2) of the Health and Medicines Act 1988 to use a company as a vehicle to exploit IP they own. This brings these NHS bodies into line with Independent Providers of NHS Services and with other Public Sector Research Establishments.

The implementation of Research Governance in the NHS places a duty on the Trust, to have in place, a mechanism for the exploitation of IP arising from its employees. Innovation in the NHS also occurs in the delivery of patient care and in the education and training of employees. This document details a policy for the effective management of IP within the Trust taking into account the recommendations set down in the national guidance framework document.

### 2. Aims

- To increase the awareness and understanding of IP issues by Trust staff through education.
- Establish an effective procedure for technology audit and the protection of IP owned by the Trust.
- Facilitate the appropriate exploitation of Trust IP
- Manage an IP portfolio in partnership with the national NHS system to maximise the Trust's IP assets.
- Ensure that Trust IP results in effective improvements in patient care.

### 3. Definition of IP and Intellectual Property Rights (IPR)

IP can be tangible or intangible. It can be defined as the products of intellectual or creative activity in the form of novel ideas, innovation or research and development that can be given legal recognition of ownership. This ownership is a tradable commodity known as the intellectual property rights (IPR). This can be a patent, copyright, design rights, trademarks or know-how. IPR can be sold or licensed exclusively or non-exclusively. IP can be generated where R&D, delivery or management of care or other creative work is being undertaken.

Where the IP can be protected by the application for a patent, it is imperative that the invention remains confidential. Prior disclosure of this information will render the invention non-patentable in many regions of the world (See section 6.2.1.).

### 4. Persons Covered by this Policy

- All staff that are full or part-time employees of the Trust whether generated in the course of a working day or outside normal working hours and/or away from the place of work, where IP relates to their area of employment by the Trust.
- Staff with contracts of employment with the Trust whose payroll costs are partially or fully funded by another party (e.g. medical charity, Government Department) unless the contract between the Trust and that party assigns ownership of the IP to that party.

- Staff employed part-time by the Trust who are self employed or otherwise employed part-time. Where the IP generated during this non-Trust employment, which is in the specialist area of the Trust employment, the Trust owns the IP. Flexibility may be exercised where the non-Trust employment gives greater opportunity for IP to arise.
- Trainee professional hosted by the Trust who generates IP during the course of their training.
- Trust staff seconded to another organisation or employees of another organisation hosted by the Trust under contract subject to the terms defined in the contract between the Trust and that organisation.

When IP is generated, and not exploited by the Trust, the IP will be assigned to the inventor who may wish to pursue its further development independently. Where protection is acquired and the invention no longer deemed to have suitable commercial potential the IP will be assigned to the inventor upon request.

#### **4.1 Students**

Students, who are not employees of the Trust, are not subject to the provisions relating to the provisions in the 1977 Patent Act or in the Copyright, Designs and Patents Act 1988. However, students engaging in research for the Trust will sign a confidentiality agreement that will also require the student to disclose details of the invention and assign the rights to the Trust on request. In consideration of all issues relating to IP the student is treated on a par with Trust staff. Other researchers at the Trust who are neither staff nor students e.g. Senior Research Fellows and other emeritus staff will be brought within the scope of this agreement.

#### **4.2 Independent Providers of Services**

Independent Providers of Services who generate IP from research funded by the NHS are required to inform the appropriate party and share the benefits of its commercialisation. Where IP is assigned to the NHS Trust, the Independent Provider of Services will benefit under the revenue sharing scheme of that Trust.

### **5. IP Management Structure**

It is the responsibility of the appointed IP Lead to manage and protect IP for the Trust. This will usually be a member of staff in the R&D Office. The Trust is a member of the technology transfer organisation, Ventures for Health (see paragraph 7), who will provide the necessary support and advice in managing IP. Where Ventures for Health do not consider the invention for protection the Trust may wish to secure the IPR independently. The staff of Ventures for Health may be contracted in this instance to manage the process of securing the IPR for the Trust at an agreed market rate.

The staff of Ventures for Health will also advise on the appropriate mode of protection of IPR with respect to the registered processes of design rights and trade marks.

### **6. Ownership of IP**

In accordance with the Patents Act 1977 and Copyright, Designs and Patents Act 1988, the ownership of IP, in most instances, will reside with the employing Trust. Any activities outside of the normal duties of the employee that generate IP will belong to the employee. The exception to this is when the employee is directed to perform other duties as part of their employment where the generation of IP might reasonably be expected to result.

#### **6.1 Contracts of Employment**

The Trust will include a statement with reference to IP in the contract of employment for all new staff. For existing staff, the policy will be incorporated into the terms and conditions of employment. A copy of the policy will be made available to staff, and they will be asked to confirm in writing that their acceptance of the policy. A statement will be included in the Licence to Operate agreement for those working on a Licence to operate basis.

Temporary staff supplied via External Employment Agencies will be covered by an agreement drawn up between the Trust and the External Employment Agencies.

#### **6.2 Collaborative Projects**

When work/research is conducted by an employee, in partnership with another organisation, a formal agreement stating ownership (or sharing) of generated IP is required. In the instance where the third party is Imperial College, a

framework document is in place with the Trust, detailing the principles of assessment of contribution and ownership and revenue share resulting from exploitation of the IP (Appendix I).

### **6.3 Shared Materials**

Materials are defined as equipment, reagents and biological materials, including cell lines, tissues, bacterial strains, plasmids and viruses. When such materials are distributed to other researchers or used in a project they should be subject to a Material Transfer Agreement. (MTA). This agreement should define the limitations of use of the material and recognises the interest in the intellectual property that may arise from its use. This agreement must be in place prior to distribution and use of the material. The use of trade marks and design rights associated with the aforementioned materials should also be the subject of this agreement.

### **6.4 Responsibility of Inventors**

Employees are obliged to inform the Trust of identified or potential IP resulting from their activities. This should be done via the R&D Manager or the staff of Ventures for Health. Staff must not, under any circumstances, disclose before protection, sell, assign, licence, give or otherwise trade IP without the Trust's agreement.

#### **6.4.1 Disclosure**

Disclosure of an invention can take many forms and can result in an idea being lost to exploitation and render it unprotectable. Disclosure may be in the form of:

- A written article that is circulated whether published officially or not.
- A conversation in a public place.
- A poster presentation
- An oral presentation in a public meeting (a minority of closed meetings with invited attendees do not count as disclosure)
- An abstract
- Conversations that are not subject to a Confidentiality Agreement.

#### **6.4.2 Publication**

The right to obtain a patent may be lost as a result of the public disclosure of an invention in the form of a published scientific paper or meetings abstract. This information will be cited as "prior art" to the invention. In the event that a disclosure is imminent the IP Lead of the Trust should be informed. The drafting of a patent application need not necessarily delay a publication.

### **6.5 Due Diligence**

When an invention, or potential invention is notified, a process of due diligence will occur to identify all of the inventors, their employment status and their contribution to the invention and ensure that there has been no prior disclosure. This will be carried out at the earliest opportunity for the purposes of filing a patent application, if appropriate. The staff will provide all records as necessary to facilitate the process.

### **6.6 Disputes of Ownership**

If the ownership of IP is questioned all records relating to the invention will be examined by the Chief Executive Officer of the Trust who will make a final decision taking professional advice as necessary. When this dispute involves an Imperial College employee, a mechanism is defined in the framework agreement for IP to resolve the issue.

### **6.7 Record Keeping**

The guidelines laid down in the United States of America for record keeping in a scientific environment should be adhered to as closely as is practically possible. All laboratory work should be recorded in a notebook with a

permanent binding, which must be signed, dated and witnessed as a true record of the experiment/procedure, preferably by someone who is familiar with the work but not a co-inventor. All experiments should be described, even if they are negative results as this illustrates how the invention has been put into practice.

All records should be made in permanent ink and derogatory remarks should be avoided. Statement of fact should be recorded and it is preferable not to express opinions that could lead to misinterpretation. Errors should be crossed through, as should blank pages, and correction fluid should not be used.

Supporting records such as photographs and computer printouts should be added to the notes and signed and dated. When completed, the notebook should be stored in a safe place and not treated as freely available information.

Records should be maintained, including copies of all correspondence and notes of telephone conversations and meetings. Records should also show relevant dates and actions agreed.

## **7. Provision of IP Skills**

The Trust has a designated IP Lead who is the point of contact for matters relating to IP within the Trust. The Trust is a full member of Ventures for Health. This is a specialised technology transfer office within the NHS which acts in the interest of the Trust to promote IP issues to improve patient care. The staff of Ventures for Health are accountable to the appointed Project Lead of the leading member organisation. The IP Lead of the Trust is a member of the management committee of Ventures for Health and should ensure that the Trust is receiving the required service from its staff to manage and exploit the Trust's IP.

Ventures for Health has received support for 4 years, primarily from the DTI and the OST, to establish a technology transfer office in west London as the preferred route of identification and management of the Trust's IP. Additional IP expertise will be utilised as appropriate in consultation with the IP Lead for the Trust.

### **7.1 Exploitation of IP**

It is the responsibility of the Trust to identify and exploit the IP generated by the research conducted through the NHS R&D levy. The Research Governance Framework for Health and social Care states that the employers should ensure that agreements are in place between them and their staff and between them and research funders and care organisations covering the issues of ownership, exploitation and revenue arising from IP generated by research conducted by their employees. As a member of Ventures for Health the Trust has the capacity to manage its IP.

### **7.2 IP Audits**

There is no formal obligation to capture IP through a process of technology audit. Ventures for Health will however employ the auditing process to identify IP for the Trust and evaluate the inventions prior to the decision of whether to exploit or not.

### **7.3 Decisions on Exploitation**

Potential IP will be assessed by Ventures for Health and the R&D Department of the Trust. When an invention is not taken forward for exploitation the inventor will always be informed of the rationale behind the decision. Ventures for Health have a defined mechanism for the decision making process.

### **7.4 Contract Negotiations**

Contracts for research will be processed by the Trust's Contracts Manager and should be scrutinised for clauses relating to IPR. All clauses should be negotiated to be fair and equitable. When material/equipment is used from a third party Material Transfer Agreements (MTA) should always be in place clarifying the interest of the third party in any resulting IP.

Ventures for Health will negotiate the licence, sale or transfer of IP to another organisation in the best interests of the Trust. The Trust may wish to have a representative/advisor present during this time.

## 7.5 Spin-Off Companies

Section 5 of the Health and Social Care Act 2001 amends Section 7 (2) of the Health and Medicine Act 1988 so as to enable the Secretary of State and certain NHS bodies (including Trusts and Primary Care Trusts) to form, or participate in the formation of companies for income generation purposes. In such cases the Trust is subject to statutory and other limitations, and this, activity should not detract from the performance by the Trust of its functions or obligations under NHS contracts.

The Trust taking a shareholding in the spin-off company will have a Trust employee nominated, by the Trust Chief Executive, to its Board or as an observer to the Board, with a residual right to appoint a Director if it desires. This employee will have sole responsibility to support the development of the company, providing this does not give rise to a conflict of interest with the employee's NHS duties.

NHS employees can participate in the commercialisation of IP that they have generated, provided that they have created or contributed knowledge to its commercial value, have a potentially important role in the successful commercialisation and that conditions ensuring probity can be met.

## 8. Protection of IP

Ventures for Health will provide the necessary services to manage the process for the protection of IP in the best interests of the Trust.

## 9. Budget

Ventures for Health will cover the expense of agreed patent and legal costs related to the protection of IP. These costs will be recovered from the revenue generated from exploitation of the invention. When Ventures for Health does not take an idea forward the Trust will allocate funds from its budget should it wish to pursue protection of the IP.

## 10. Revenue-Sharing With Inventors

A patent provides the mechanism for a monopoly to exploit an invention and encourages further innovation. To encourage staff to contribute substantially to the generation of IP, Ventures for Health will operate a reward for inventors policy in respect of IP protection, and commercialisation thereof, that will be shared with the Trust and the inventor according to a specific formula (Table 1). In cases where there are a number of inventors the income allocated will be divided between them. When a proportion of the inventors is an Imperial College employee, the share will be in accordance with the assessment of contribution defined in the framework agreement. In all cases the shared revenue will be net of any protection and exploitation costs incurred.

Table 1. **Revenue-Sharing**

<b>Cumulative Revenue</b>	<b>Net</b>	<b>Inventors per Invention</b>	<b>Trust</b>	<b>Department</b>
First £50k		75%	12.5%	12.5%
Next £200k		50%	25.0%	25.0%
Over £250k		25%	37.5%	37.5%

The above figures are net of the 30% apportioned to Ventures for Health and after deduction of the patent and legal expenditure incurred. These figures may vary slightly from project to project as individual circumstances and third parties associated with each technology are assessed.

Income arising from IP can be in a variety of different forms and the flow of these funds is difficult to predict. It has therefore been agreed at the national level (3) that:

- The amount of revenue that a Trust may retain resulting from the exploitation of an invention is stated in the National Policy document (4).
- This income and its use should be reported at discussions with commissioners about the subsequent financial year.
- Where the income in any year is greater than this, then the NHS body should present spending plans to its health commissioners.
- When these plans cover several years for a lump of income, commissioners may ask to defer this planned expenditure and use the funds for patient care in the short term if there is particular pressure on their budgets to meet priorities and planning targets.
- The same flexibility should also apply to Primary Care Trusts themselves where they undertake IP exploitation with the same powers.

## 11. Copyright

There is no official register for copyright. It is an unregistered right (unlike patents, registered designs or trade marks). So, there is no official action to take, (no application to make, forms to fill in or fees to pay). Copyright comes into effect immediately, as soon as something that can be protected is created and "fixed" in some way, e.g. on paper, on film, via sound recording, as an electronic record on the internet, etc.

You should mark your copyright work with the copyright symbol © followed by your name and the date, to warn others against copying it, but it is not legally necessary in the UK.

The Trust will normally grant a free licence to the copyright of any work published in a recognised scientific, technical, professional or management journal or book. The Trust will not grant such a licence for materials created by a member of staff during the course of and related to their employment, including but not limited to:

- Course or training material
- Patient information
- Software programmes
- Designs, specification or other works which may be necessary to protect rights in commercially exploitable IP

The Trust will respect the moral rights of its employees to be named as authors in copyright materials.

The type of works that copyright protects are:

- original literary works, e.g. novels, instruction manuals, computer programs, lyrics for songs, articles in newspapers, some types of databases, but not names or titles;
- original dramatic works, including works of dance or mime;
- original musical works;
- original artistic works, e.g. paintings, engravings, photographs, sculptures, collages, works of architecture, technical drawings, diagrams, maps, logos;
- published editions of works, i.e. the typographical arrangement of a publication;
- sound recordings, which may be recordings on any medium, e.g. tape or compact disc, and may be recordings of other copyright works, e.g. musical or literary;
- films, including videos; and

- broadcasts and cable programmes.

All of these works above are protected by copyright, regardless of the medium in which they exist and this includes the internet. You should also note that copyright does not protect ideas. It protects the way the idea is expressed in a piece of work, but it does not protect the idea itself.

Under the Copyright, Designs and Patents Act 1988, the author (other than an employees in relation to works generated in the course of their duties of employment) is entitled to assert their moral rights in respect of the work created even where ownership is vested in a third party such as the Trust. This means that the author is entitled to have the integrity of the work respected, which would include the way in which it is used and the context in which it is included.