

**A submission to the Gowers Review of Intellectual Property Team
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Executive summary

The Stockholm Network believes the Gowers Review of Intellectual Property is very timely, and we appreciate having been asked to submit evidence to this important process.

UK policy on intellectual property (IP) is determined not just by the British government but also by IP and competition policy at the European Union level, which is why the focus of this submission is on current European IP issues and the need to improve them. Our main recommendation for the UK is to take a more pro-active role at the pan-European level and lead the other Member States in discussions that today are stalled or non-existent.

Key Findings and Main Recommendations by the Stockholm Network

- Empirical research suggests that the UK is one of the global beneficiaries of IP-based activities, and that the country is one of the world's leaders in this field.
- However, empirical evidence also suggests that the UK is losing ground to other countries. We should be mindful of this worrying trend.
- The UK needs to be more pro-active at the pan-European level, both through the European Parliament and the European Commission.
- The UK needs to urge EU policymakers to revisit their approach to the balance between competition rules and intellectual property rights, by providing more emphasis on the latter in the context of Article 82.
- The UK and the EU should look into both structural and educational ways of encouraging technological transfer in Europe, including the creation of a pan-European framework similar to the Bayh-Dole legislation in the US.
- The UK should expand the use of Supplementary Protection Certificate (SPC) in the pharmaceutical sector, including in the case of combination products.

- The UK should also be mindful of the fact that other pharmaceutical IP elements should be significantly improved, both at the UK and the EU levels. These include re-thinking the damaging policy of parallel imports, granting of paediatric drug exclusivity for significant periods, lifting price restrictions and allowing the use of brands for the purpose of providing reliable information to consumers.
- The UK should encourage a fast track application process, cost reductions, and the cutting of red tape for small and medium sized enterprises (SMEs) trying to obtain patents.
- The UK should take the lead in making all parties ratify the London Agreement, and then getting the discussions of a Community Patent back on track.
- The UK should take the lead in reviving the Computer Implemented Inventions Directive in its original form in order to encourage technological innovation in Europe.
- The UK should promote strengthening the WTO TRIPS Agreement and work against further developments of so-called 'TRIPS-flexibilities'.

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1.0 About the Stockholm Network

The Stockholm Network (SN) is the leading pan-European think tank and market oriented network.

It is a one-stop shop for organisations seeking to work with Europe's brightest policymakers and thinkers. Today, the Stockholm Network brings together more than 120 market-oriented think tanks from across Europe, giving us the capacity to deliver local messages and locally-tailored global messages across the EU and beyond.

Combined, think tanks in our network publish thousands of op-eds in the high quality European press, produce many hundreds of publications, and hold a wide range of conferences, seminars and meetings. As such, the Stockholm Network and its members influence many millions of Europeans every year.

1.1 About the SN IP and Competition Programme

The Stockholm Network Intellectual Property and Competition Programme was established in January 2005.

Dealing with the field of intellectual property across the board (including in its monthly bulletin - Know-IP™), the Programme aims to achieve three key objectives:

First, to make the field of intellectual property more mainstream as well as accessible to the general public. It seems that, currently, the field of intellectual property, despite having huge economic, social and political implications to the public as a whole, is considered esoteric, technical and to some extent 'grey'. This gap should be bridged.

Second, to increase the interaction between specialists focusing on different aspects of intellectual property rights. A positive effect of the growing importance and impact of the IP field is professionalism and specialisation. This, however, also leads to an undesirable detachment between different elements and themes of IP, which are becoming more and more 'divorced' from each other. For example, copyright, patent and trademark specialists, as well as those dealing with the legal, economic and political aspects of IPRs, seem to operate on parallel tracks. A more active debate between IP specialists will help us to obtain more comprehensive and up-to-date information about developments in the IP field as a whole.

Finally, and perhaps most importantly, the SN IP and Competition Programme aims to encourage discussion, as well as debates, on different burning IP issues. However, such discussions should be as informed as possible. We aim neither to idolise IPRs, nor to demonise them. Rather it is important to see IPRs as a policy toolbox aimed at achieving two social goals: to provide incentives to innovate and develop new knowledge and informational products in the future; to ensure wide public access to such products in the present.

2.0 General Issues

2.1 Innovation, Competitiveness and IPRs under the Lisbon

Agenda- The need for more proactive involvement by the UK at the pan-European level

European Heads of State decided in 2000 to embark on an ambitious reform agenda now known as the Lisbon Agenda. The EU Member States committed themselves to becoming 'the most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs and greater social inclusion' by 2010. More specifically in the context of innovation and intellectual property, the leaders decided to increase R&D spending in the region from a modest 1.96% to 3%, and called for a Community Patent to be available by 2001.¹

Five years after the Lisbon Agenda was agreed upon and with less than five years left to go, the prospects of reaching the goals are not encouraging. The EU has fallen further behind key competitors such as the USA and Japan over the last decade. And according to the European Innovation Scoreboard for 2005 the gap between the EU and its competitors is widening rather than narrowing, despite recent efforts to encourage innovation.²

The process has been so disappointingly slow that it was decided to re-launch the Lisbon Agenda last year, only this time under the name 'Strategy for Growth and Jobs'.

The renewed Lisbon Agenda urged Member States to press ahead with the implementation of the National Reform Programmes. Although a decentralised process has its merits, it seems like the EU has strayed away from the initial focus of the Lisbon Agenda, which was to build a leading and sustainable knowledge-

¹ European Commission www.europa.int?comm/internal_market/en/indprop/patent/ec/lisbon03-00.htm

² The European TrendChart <http://trendchart.cordis.lu/>

based economy. In fact, the renewed Lisbon Agenda contains elements of protectionism, and the so-called European Social Model is seen as something that needs to be shielded from the forces of globalisation and international competition. If the EU is still committed to becoming a sustainable knowledge-based economy, it should concentrate its efforts on building the environment needed for innovation to flourish, rather than spending its budget on subsidising sectors where it has no comparative advantages.

In this context, a healthy and robust IP environment should be part of the future ambitions of the EU region in general and the UK in particular. IP is becoming one of the most influential issues in today's knowledge-based society. In Europe, IP policies and specific forms of IPRs are rapidly capturing the attention of policy makers and the public as a whole. They touch upon some fundamental issues, such as intra-EU harmonisation, its innovation climate, antitrust and competition rules, and the EU's ability to support specific sectors, such as pharmaceuticals, biotechnology and information technology.

Nevertheless, despite recognising the importance of IPRs, the EU has failed to adopt a coherent and proactive approach for improving its IP environment. As discussed in the document below, the EU currently suffers from some serious structural deficiencies in the IP field across the board. This in turn will also affect the UK negatively.

The UK IP environment is closely linked to and influenced by the EU environment. As such, the Stockholm Network believes the UK should take an even more proactive role at the pan-European level. This involvement should be both at the legislative (European Parliament) and the executive (European Commission) levels. The European Commission is of particular importance as it would seem that despite its recent initiatives, such the Computer Implemented Inventions Directive (CIID), these initiatives have been significantly modified and even brought to a halt by the European Parliament.

2.2 The UK's Global IP Performance – Empirical Evidence

In terms of general patenting activities, data suggests that the UK is one of the European leaders (though not *the* leader) in its ability to obtain patents both in the EU and globally.³ In 2002 the UK was among the leading patenting countries globally, with a 1.7% share of triadic patents (Table 1).⁴ In absolute terms, the UK is ranked 5th, following Japan (35.6%), the US (35%), Germany (14.1%) and France (4.8%).

But between 1991 and 2002, the UK experienced a relative decline in its global share of patenting activities. Figure 1 shows that the UK was ranked only 15th in terms of patent intensity (patents divided by population) in 2000.⁵ This trend is also supported by the 2005 European Innovation Scoreboard (EIS) Report, where the UK is considered a country with an 'average' IP performance (Figure 2).

The EIS Report aims to provide a more comprehensive approach of comparing countries' ability to capture various forms of IPRs (in this case, patents, trademarks and designs), by using different sets of IP indicators to measure innovation outputs.⁶ The EIS Report for 2005 makes a distinction between four groups of countries in Europe: leading countries, average countries, countries that are catching up and countries that are losing ground.⁷

One of the most common ways of measuring the volume of IP-related transactions is to look at royalties and license fees. The terms royalties and licence fees broadly refer to 'the exchange of payments and receipts between residents and non-residents for the authorised use of intangible, non-produced, non-financial assets and proprietary rights (such as patents, copyrights,

³ These figure are based on the the OECD's Compendium of Patent Statistics (2005), which measures countries' performances based on *triadic patents families*. The term *triadic patents families* broadly refer to a set of patents (originating from the priority filing) granted the European the Japanese and US patent offices (EPO, JPO and USPTO)

⁴ *Ibid*

⁵ . OECD, 2005, p.16

⁶ . European Commission DG Enterprise, *Methodology Report on European Innovation Scoreboard 2005*(Brussels: 20 May 2005), p. 9

⁷ . EIS Report 2005,p.12

trademarks, industrial processes, franchises, etc.) and with the use, through licensing agreements, of produced originals or prototypes (such as manuscripts and films).⁸

For the purpose of this submission we have extracted and compiled data from the OECD Services Statistics on International Trade in Service - Royalties and Licence Fees – for the years 1994-1993.⁹

The data suggests that over the last decade the UK has been one of the biggest net beneficiaries of IP- related transactions among the OECD countries. The UK has been able to more than double its net balance from IP-related transactions from 1.2 billion US\$ in 1993 to over 2.5 billion US\$ in 2003 (Table 2).

⁸. OECD. Statistics on International Trade in Service (Paris: 2005), p. 22

⁹. OECD. Statistics on International Trade in Service,2005

Table 1 - Share of countries in total Triadic patent families 2002
(Calculations and compilation based on OECD, Patent Database, December 2005).¹⁰

%	1991	2002	Triadic Patent Families, 2002	Changes in shares of countries/economies ² , 1991-2002
World	100.00	100.00	51,502	
OECD	98.93	98.04	50,494	
United States	34.17	35.58	18,324	1.41
European Union	30.66	31.49	16,217	0.83
Japan	29.68	25.62	13,195	-4.06
Germany	12.28	14.12	7,271	1.83
France	5.95	4.75	2,447	-1.20
United Kingdom	4.18	3.97	2,045	-0.22
Netherlands	1.90	1.88	966	-0.02
Switzerland	2.41	1.79	924	-0.62
Sweden	1.31	1.74	896	0.43
Italy	2.21	1.63	840	-0.58
Canada	0.92	1.28	661	0.37
Korea	0.31	1.22	630	0.91
Finland	0.54	1.15	594	0.61
Belgium	0.80	0.77	397	-0.03
Australia	0.52	0.71	367	0.19
Israel	0.36	0.64	328	0.28
Austria	0.58	0.55	282	-0.03
Denmark	0.35	0.42	216	0.07
China	0.04	0.28	144	0.24
Spain	0.24	0.23	120	0.00
Norway	0.20	0.21	106	0.01
Chinese Taipei	0.06	0.20	102	0.14
Singapore	0.07	0.16	85	0.10
India	0.03	0.15	78	0.12
Ireland	0.09	0.12	60	0.03
Russian Federation	0.13	0.11	59	-0.01
New Zealand	0.06	0.08	41	0.02
South Africa	0.06	0.07	38	0.02
Brazil	0.02	0.07	36	0.05
Hong Kong, China	0.05	0.06	32	0.01
Hungary	0.07	0.05	27	-0.02
Luxembourg	0.03	0.04	21	0.01
Mexico	0.02	0.03	15	0.01
Czech Republic	0.03	0.02	12	-0.01
Poland	0.03	0.02	9	-0.01
Turkey	0.00	0.02	9	0.02
Argentina	0.02	0.02	8	0.00
Iceland	0.01	0.02	8	0.01
Greece	0.02	0.01	7	0.00
Portugal	0.01	0.01	6	0.00
Chile	0.00	0.01	4	0.00
Romania	0.00	0.00	2	0.00
Malta	0.00	0.00	1	0.00
Latvia	0.00	0.00	0	

¹⁰. This is an extract from Pugatch M., *Assessment of Sweden's Intellectual Property Performance* (forthcoming Timbro: 2006)

Slovak Republic	0.00	0.00	
Cyprus	0.01	0.00	
Estonia	0.00	0.00	
Lithuania	0.00	0.00	
Slovenia	0.01	0.00	
		131.32	

Note: Patent counts are based on the inventor's country of residence, the earliest priority date and fractional counts.
1. Patents all applied for at the EPO, USPTO and JPO. Figures for 2000 to 2002 are estimates.

Figure 1- Triadic patent families per million population, 2002 & 1991
(Source OECD, Patent Database, December 2005)

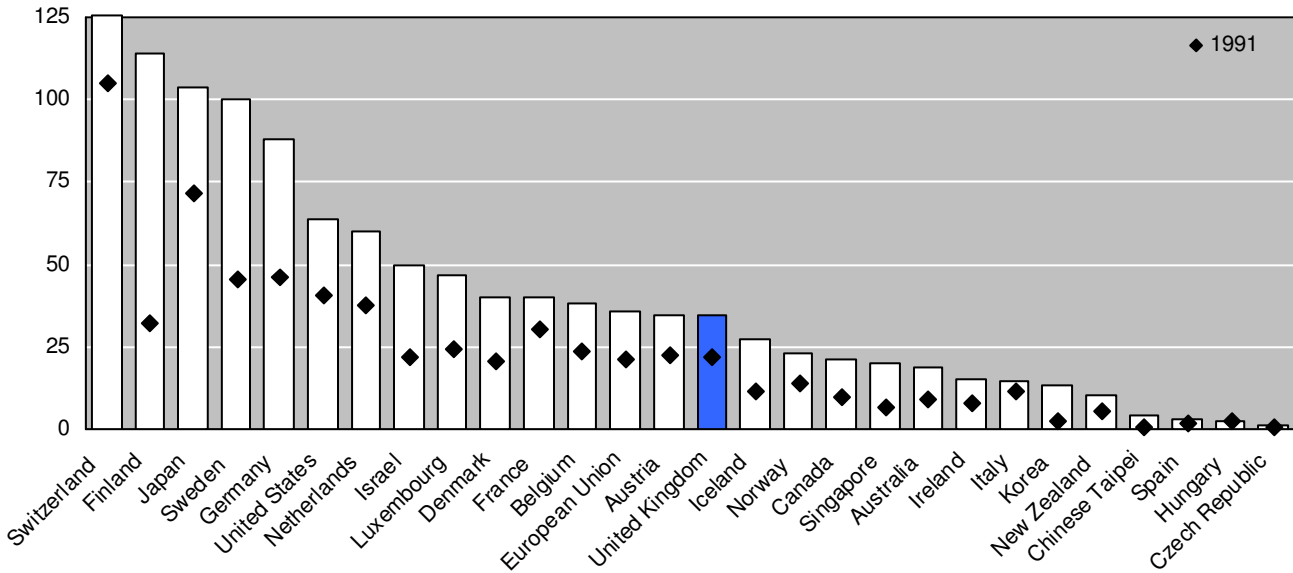
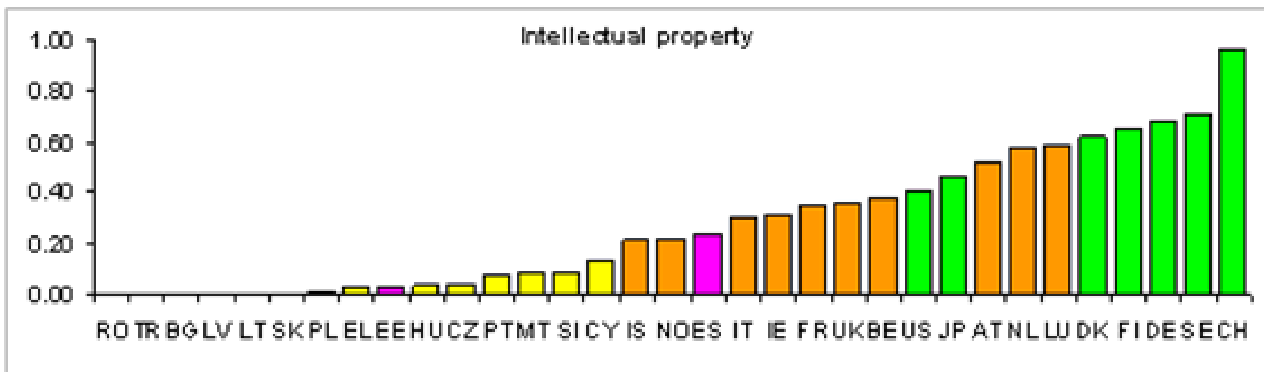


Figure 2- EIS 2005 Report ranks the UK as a country with an average IP performance (source EIS Report 2005)



**Table 2 -Intellectual property transactions - royalties and license fees
1993 – 2004 (\$US Million)**

(Calculations and compilation based on OECD Statistics on International Trade in Service, 2005 vol. 2)¹¹

		1993	1994	1995	1996	1997	1998	1999	2001	2002	2003	2004
OECD	Net				5108	5917	3812	5957	8118	5156	5088	4552
	Credits				58889	61137	64627	71360	78129	75782	81570	92880
	Debit				53781	55220	60815	65403	70011	70626	76482	88328
EU-15	Net	-6344	-6105	-8296	-	-	-	-	-	-	-	-
					11107	10152	13363	12144	11336	12704	12699	17304
	Credits	11932	14015	15607	18034	18425	19269	20790	20906	20546	22611	27280
	Debit	18276	20120	23903	29141	28577	32632	32934	32242	33250	35310	44584
Germany	Net	-2374	-2107	-2806	-2506	-2504	-2298	-2018	-2675	-2197	-1374	-996
	Credits	2058	2398	3131	3378	3225	3340	3121	2919	3299	3784	4241
	Debit	4432	4505	5937	5884	5729	5638	5139	5594	5496	5158	5237
Finland	Net	-238	-246	-331	-398	-409	-307	275	320	53	-44	-115
	Credits	89	76	59	66	94	106	648	883	585	559	500
	Debit	327	322	390	464	503	413	373	563	532	603	615
France	Net	-342	-375	-465	-768	-430	-383	-300	266	716	1432	1494
	Credits	1455	1527	1855	1885	2044	2331	1982	2313	2604	3326	3930
	Debit	1797	1902	2320	2653	2474	2714	2282	2047	1888	1894	2436
Italy	Net	-1112	-1089	-731	-1065	-415	-850	-819	-636	-864	-742	-1181
	Credits	466	634	876	679	1165	732	556	555	438	527	514
	Debit	1578	1723	1607	1744	1580	1582	1375	1191	1302	1269	1695
Ireland	Net	-1325	-1821	-2592	-3315	-3969	-6026	-6528	-7413	-9500	-	-
											10728	15910
	Credits	66	90	132	100	118	172	416	509	248	280	205
	Debit	1391	1911	2724	3415	4087	6198	6944	7922	9748	11008	16115
UK	Net	1236	1369	1839	329	657	422	1306	1528	1696	1765	2513
	Credits	3397	3974	4692	6635	6791	7072	8239	8154	8166	8672	9886
	Debit	2161	2605	2853	6306	6134	6650	6933	6626	6470	6907	7373
Sweden	Net	157	391	-41	55	80	186	258	367	630	620	1054
	Credits	746	1151	789	889	934	1154	1408	1282	1512	1517	2325
	Debit	589	760	830	834	854	968	1150	915	882	897	1271
US	Net	16663	20860	23370	24633	24067	24391	26563	26765	24158	24984	28178
	Credits	21695	26712	30289	32470	33228	35626	39670	43233	40696	44219	48227
	Debit	5032	5852	6919	7837	9161	11235	13107	16468	16538	19235	20049
Japan	Net	-3330	-3113	-3416	-3151	-2310	-1563	-1671	-778	-659	-583	1287
	Credits	3863	5180	6026	6671	7306	7379	8173	10230	10441	10420	12274
	Debit	7193	8293	9442	9822	9616	8942	9844	11008	11100	11003	10987

¹¹. This is an extract from Pugatch M., *Assessment of Sweden's Intellectual Property Performance* (forthcoming Timbro: 2006)

2.3 Competition Rules and IPRs in Europe

There is an inherent tension between supporting intellectual property rights on the one hand and enforcing strong anti-trust rules on the other hand. This is because IPRs create temporary monopolies, and monopolies are exactly what competition rules seek to remedy.

This tension between European competition rules, which are laid down in Articles 81 and 82 of the EC Treaty, and IPRs has become especially evident in the EU recently when Directorate General (DG) Competition, responsible for ensuring fair competition in Europe, moved far beyond the Magill Principle of 1995. The *Magill* case established that IPRs should not be abused in a manner that prevents the introduction of new products to the market.¹² Now, however, the strategy of DG Competition seems no longer to be aimed at preventing the abuse of IPRs in cases that involve the possible introduction of new products to the market. Rather, their strategy seems to be focusing on forcing IP owners to license their IPRs to competing companies that seek to provide more or less the same products. This is especially true in the *Commission vs. Microsoft* case, where Microsoft has been forced not only to license its IPRs to competitors, but also to provide them with technical assistance. Rather than developing new products or technology based on Microsoft's innovation, these companies were actually seeking to provide consumers with similar or even identical products. The issue here is not about sacrificing intellectual property rights for the noble cause of providing new products to consumers (that otherwise would not have been developed) but about the profits of competing companies. The question is therefore whether DG Competition has in fact sacrificed the principle of IPRs to promote competition.

The protective function of European competition rules and Article 82 in particular often appears to work so as to insulate smaller companies from the effects of

¹² European Courts of Justice http://curia.eu.int/en/content/juris/index_form.htm

competition, rather than to safeguard the efficient functioning of markets. If this is a true function of Article 82, there is a danger that competition law may actually have the effect of unfairly constraining successful undertakings that have achieved high market shares by bringing to market innovative, successful products that are popular with the majority of consumers.¹³

The Stockholm Network is concerned that European Union policy-makers are undermining the importance of predictable and efficient IPRs by adopting hawkish antitrust remedies. We would therefore recommend that the UK urges EU authorities to clarify their approach to the two codes. With the right policies in place, the one principle need not exclude the other. Article 82 should be interpreted carefully to make sure competition rules are invoked only in cases where it is clear that IP has been abused in a manner that prevents the creation of new products to the public.

2.4 Technology Transfer and Public Private Partnerships in the EU

Commercialisation of technology stemming from governmental and public research institutions has been identified as one of the challenges Europe is facing when trying to catch up with its competitors and become the world's leading knowledge-based economy. Interestingly, Europe is doing well in fundamental research, so the problem seems to be technology transfer or transforming technology to industry.¹⁴ To adopt an IP framework that efficiently supports technology transfer activities should therefore be an absolute priority for the EU.

The most prominent examples of successful approaches to encourage technology transfer are the Patent and Trademark Law Amendments Act (commonly referred to as the Bayh-Dole Act) and the Federal Technology Transfer Act (also known as the Stevenson-Wydler Act), which were adopted by

¹³ Curley, D. "Balancing Intellectual Property Rights and Competition Law in a Dynamic, Knowledge-Based European Economy" in, Pugatch, M.P., ed. *The Intellectual Property Debate: Perspectives from Law, Economics and Political Economy* (Cheltenham, UK: Edward Elgar, forthcoming: July 2006)

¹⁴ C. Garner, SN Know IP Volume 2, Issue 2: 2006

the US government in the early and mid-1980s.¹⁵ These acts are both examples of public-private partnerships (PPP) designed to promote the commercialisation of federally sponsored research and development (R&D) through cooperation between the research community, industry and state and local community. The results of the legislations are remarkable; before the Acts were adopted in 1980, fewer than 250 patents were issued to U.S. universities each year and discoveries were seldom commercialised. In contrast, between 1993 and 2000, these universities were granted some 20,000 patents and more than 3000 new companies were established. In 2003 alone, almost 4000 patents were issued to universities. Last but not least, all these activities generated income of more than 1.2 billion US\$ to academic and government institutions.¹⁶

Rather than focusing on these impressive results, some critics have argued that the public nature of universities and publicly funded research entities makes them less suited for this commercially-orientated approach to technology transfer.

The Stockholm Network believes that the results of the Bayh-Dole and Stevenson-Wydler Acts suggest the UK and the European Union should look into the possibility of developing a similar approach to promote technology transfer. Although there are frameworks already in place in the European Union to encourage these activities, they are clearly not working as well as they could. The UK as the financial centre of Europe and with its world-leading universities should definitely take a lead in this process. Alternatively, the UK and the EU should focus on less structural approaches such as to encourage risk-averse Europeans to embrace international competition and change. A post-WW2 mindset that puts safety and protectionism over risk-taking and innovation dominates many levels of European society. The remedy must therefore be targeted at all levels from schools and universities to businesses.¹⁷

¹⁵ US Patent Office http://www.uspto.gov/web/offices/pac/mpep/consolidated_laws.pdf

¹⁶ Association of Universities Technology Managers, <http://www.autm.org>

¹⁷ For more information on this see the Aho Group Report http://europa.eu.int/invest-in-research/action/2006_ahogroup_en.htm

3.0 Specific Issues

3.1 The Importance of IP Protection in the Pharmaceutical Field

The development of innovative pharmaceutical products is probably one the most (if not the most) lengthy, costly and risky process undertaken by any industry.

All potentially new medicines have to demonstrate their safety and efficacy before being approved for market use. This is done through a complex and lengthy process of clinical trials which last on average more than 14 years.¹⁸ Estimates suggest that of every 5,000 new chemical entities (NCEs) screened, on average, only five are tested in clinical trials and only one of those is approved for patient use.¹⁹ Moreover, on average, only 3 out of every 10 prescription drugs available for treatment generate revenues that equal or exceed average research and development (R&D costs).²⁰

Recent estimates by the Tufts Centre for the Study of Drug Development suggest that the 'fully capitalized cost to develop a new drug, including studies conducted after receiving regulatory approval, averages 897 million US\$'.²¹ The costs and time required for the accumulation and compilation of the data included in a pharmaceutical registration file has been constantly rising. Grabowski estimates these costs at 467 million US\$, more than 60 percent of the total cost of pharmaceutical R&D.²²

¹⁸ . DiMasi, J. A., Hansen, R.W. and Grabowski, H. J. (2003), OP.CIT.; Pharmaceutical Research and Manufacturers of America (PhRMA), *Industry Profile 2003*, Chapter 1 (Washington DC: 2003)

¹⁹ . Association of the British Pharmaceutical Industry, *The Development of Medicines* (London: ABPI: 2002);

²⁰ .Grabowski, H. and Vernon, J., "Returns to R&D on New Drug Introductions in the 1980s", *Journal of Health Economics*, Vol. 13, (1999)

²¹ . Tufts Center for the Study of Drug Development. *New Release -Total Cost to Develop a New Prescription Drug, Including Cost of Post-Approval Research, is \$897 Million* (13 May 2003), <http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=29>

²² . Grabowski, H. *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries* (Duke University: July 2002), p. 5 and Figure 1; Data is adjusted to 2003 R&D expenditures

Intellectual property is of crucial importance to the future development of innovative pharmaceutical products. A study by Mansfield shows that several industries have attached great importance to the existence of patents in deciding on the development of new inventions during the early 1980s.²³ He found that in the pharmaceutical industry, between 60 to 65 percent of inventions would not have been introduced or developed in the absence of patents.

Recent developments in the pharmaceutical sector suggests that a more complex hybrid system of IPRs is emerging, where IP protection no longer depends on patents only, but also on other *sui-generis* IPRs. Therefore, maintaining a strong and supportive IP climate is one of the key fundamentals in allowing the EU and the UK to catch up with other trading blocs.

The pharmaceutical industry has its origins in Germany and Switzerland, but since the Second World War the US has become an increasingly important player. These same countries that originally gave birth to the industry continue to dominate global research-based pharmaceutical production. In 2000, the 20 largest pharmaceutical companies measured by global market share and sales were based in the US, the leading economies in Europe, and to a lesser extent Japan.²⁴

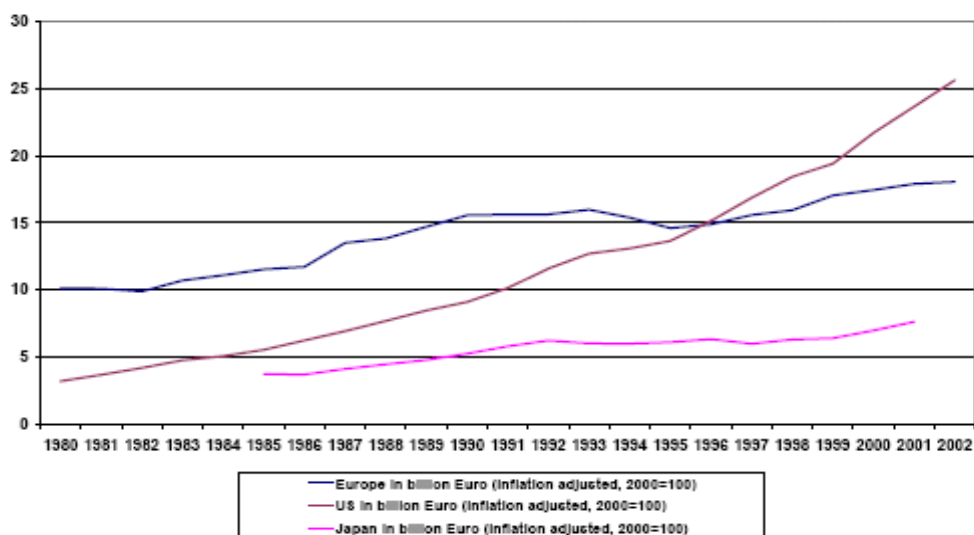
In recent decades however, there has been a steady decline in the innovative and competitive position of the EU as a developer of innovative pharmaceutical and biotechnological drugs. The US on the other hand, has taken the lead within the last 15 years, both in terms of global market share and in terms of expenditures on R&D.²⁵

²³. Mansfield, E. 'Patents and Innovation: An Empirical Study', *Management Science* (February, 1986), pp. 173-181

²⁴. Von Braun, J. and Pugatch, M. P "The Changing Face of the Pharmaceutical Industry and Intellectual Property Rights", *Journal of World Intellectual Property*, vol. 8:5 (September 2005), pp. 599-623

²⁵. Gambardella, A., Oresenigo, L., Pammolli, F. *Global Competition in Pharmaceuticals - a European Perspective*, Report prepared for the Enterprise Directorate-General of the European Commission (Luxembourg: European Communities, December 2001)

Figure 4: Pharmaceutical R&D expenditure 1980 to 2003 in billion Euro (adjusted for inflation, 2000=100)



Source: Parexel's Pharmaceutical R&D Statistical Sourcebook 2003/2004, pages 1, 289, and 296. European data based on official figures provided by EFPIA member associations. It covers all R&D spending within EFPIA countries (EU-15, excl. Lux, plus Switzerland and Norway) by national and foreign companies. The 2002 figure is an estimate. Japanese data from the JPMA Data Book 2003. US pharmaceutical spending is based on the PhRMA Annual Survey, 2003. Inflation adjustment and conversion to Euro using CPI data and exchange rates from Datastream.

Source, Charles River Associates, 2004

Several reports have highlighted the structural problems in Europe, including in IP protection that currently prevents the region from improving its global innovative and competitive position in the pharmaceutical field.²⁶

With regard to the pharmaceutical IP environment specifically, recent data also suggest that the UK is lagging behind the US. A recent statistical index developed by Pugatch (2006), which measures the strength of national pharmaceutical IP environments, on a scale of 0 to 5, suggests that the total score of the UK is 4.59 while that of the US is 4.8.²⁷

²⁶. Innovation in the pharmaceutical sector A study undertaken for the European Commission by: Charles River Associates 8th November 2004
http://europa.eu.int/comm/enterprise/pharmaceuticals/pharmacos/docs/doc2004/nov/eu_pharma_innovation_25-11-04.pdf

²⁷. Pugatch, M. P. "Measuring the Strength of National Pharmaceutical Intellectual Property Regimes: Creating a New Pharmaceutical IP Index", *Journal of World Intellectual Property*, vol. 9: 4 (forthcoming July 2006)

The pharmaceutical IP score of the UK is affected mainly in the category of barriers to full IP exploitation, including barriers to competitive pricing in the form of controls over profits (pharmaceutical prices regulations scheme – PPRs) and the absence of direct to consumer advertising of prescription drugs (DTCA). A weakness in the category of strength of exclusivity, in which parallel imports are permitted across the EU, also affects the UK score negatively (see table).

United Kingdom – pharmaceutical IP score for the Year 2005 = 4.59 (maximum value)

Category	Sub-category	Weight (%)	Input - yes=1; no=0	Calculation	Weighted
Term of exclusivity	Basic term of patent protection	40%	20.00	1.00	0.40
	Patent extension period	20%	5.00	1.00	0.20
	Data exclusivity for new drugs (NCEs)	20%	10.00	1.00	0.20
	Orphan drugs exclusivity Data	10%	10.00	3.33	0.33
	Exclusivity for new indications	5%	1.00	0.10	0.01
	Pediatric drug Exclusivity	5%	0.50	1.00	0.05
Scope of exclusivity	Coverage of pharmaceutical patents (producers and processes)	40%	1		0.40
	Coverage of biotechnology patents	20%	1		0.20
	Non-disclosure of test data	20%	1		0.20
	Non-reliance on test data	20%	1		0.20
Strength of exclusivity	Restrictions on the use of compulsory licensing	40%	1		0.40
	Prohibiting parallel imports	40%	0		0.00
	Prohibiting commercial testing during the patent term ("Bolar" provisions)	20%	1		0.20
Barriers to full IP exploitation	Absence of requirement of price negotiations as a pre-condition of product approval	30%	1		0.30
	Absence of reference pricing system	20%	1		0.20
	Absence of controls on profits	10%	0		0.00
	Post-grant opposition (as opposed to pre-grant opposition)	20%	1		0.20
	Direct to consumer advertising of prescription drugs - (DTCA)	10%	0		0.00
	Free use of brands in packaging (trademarks)	10%	1		0.10
Enforcement	Civil remedies	40%	1		0.40
	Criminal procedures	40%	1		0.40
	Policing actions against piracy and counterfeiting	20%	1		0.20
				Total	4.59

In the EU, regulation EC 1768/92 allows a pharmaceutical company to extend the term of its patent by an additional period of up to five years, as long as the effective patent life does not exceed fifteen years from the date of marketing authorisation. This mechanism is called a Supplementary Protection Certificate (SPC) and is seen as the main tool allowing pharmaceutical patent owners to

recoup some of the exclusivity lost due the extensive development periods of innovative products.²⁸

The question today for UK and EU policymakers should not be whether an SPC tool should exist, but rather "should the use of SPC tools in Europe be expanded?" This question ultimately boils down the current process of product development and to the nature of pharmaceutical products that are currently available in the market.

In most cases, pharmaceutical products include one active substance to treat a disease. However, there are an increasing number of pharmaceutical products that combine two – or more – active ingredients, each of them having its own therapeutic effect. Their combination could result in an improved or even completely new therapeutic effect. These 'cocktail drugs', which often require extensive research and clinical trials, are routinely defined as 'combination products'. Some combination products are already available to patients, while others are currently under development and in clinical trials. Provided that the protection criteria are met, a combination product should benefit from patent protection and an SPC in Europe.

In this context, a new and very important issue has recently been raised regarding the use of SPC in combination products. This issue concerns the extent to which an SPC may be granted to pharmaceutical products resulting from the combination of an off-patent active ingredient, and a patented substance that has no therapeutic effect on its own (excipient). One example of such a product is Gliadel 7.7mg Implant, which is intended to treat recurrent brain cancers. This combination product has a significant innovative value, not least on the life expectancy of patients.²⁹ The debate has also reached the doorstep of the

²⁸. Council of the European Communities. Council Regulation (EEC) No 1768/92 of 18 June 1992 Concerning the creation of Supplementary Protection Certificate for Medicinal Products (18 June 1992)

²⁹ . Campolini, M. "Innovations, Patent Extensions and Combination (Pharmaceutical) Products", Know-IP, vol.2:3 (March 2005)

European Court of Justice (Case C-431/04 MIT). The Advocate General Léger has referred to the objectives of Regulation 1768/92, which require sufficient protection to be granted to innovations that also provide an increased therapeutic efficacy. According to Advocate General Léger “the combination at stake represents a major innovation, resulting from long, costly research, which the regulation is precisely seeking to protect”. The absence of an SPC “would be likely to discourage research centres located in the Member States from investing in the development of medicinal combinations such as the one at stake”.

The granting of SPCs to pharmaceutical products, including combination products that are based on excipients, is therefore crucial to the development of new delivery systems and to improved products for the benefit of patients. It would also allow the UK to continue to attract the significant R&D investments associated with the development of these products.

SPCs are of crucial importance to the ongoing development of innovative products. The use of SPC for innovative products would first and foremost benefit patients. Additionally, the proactive use of SPC, as part of a wide range of IP policy tools, would also provide a positive contribution to the EU's attempt to regain some of its lost competitive and innovative position in the pharmaceutical and biotechnological fields. Accordingly, the UK should expand the use of SPCs to so called 'combination products', including products that combine excipients. The UK should also be mindful to the fact that other IP elements should be significantly improved, both at the UK and the EU levels. These include re-thinking the damaging policy of parallel imports, granting of paediatric drug exclusivity for significant periods, lifting price restrictions and allowing the use of brands for the purpose of providing reliable information to consumers.

3.2 Small and Medium Sized Enterprises and IPRs

Small and medium sized enterprises (SMEs) play a key role in the UK and European economies accounting for two-thirds of the continent's employment, almost 60% of economic output, and more than 99% of all enterprises.³⁰ Although most SMEs recognise the importance of intellectual property rights, many are still struggling to fully exploit the advantages of the system.

The links between innovation, intellectual property rights and funding are especially significant for knowledge-based small and medium-sized enterprises, for whom IPRs could be a make or break issue. First of all, they need IPRs to protect their innovations from being copied and commercialised by other companies. Secondly, but equally important, these businesses are dependent on IPRs to attract the investments needed to commercialise their innovation. Potential sponsors are keen to secure their investments and will be reluctant to provide money for an unprotected innovation, which can be commercialised by other companies.

With SMEs playing such a dominant role in the European economy, it is absolutely necessary that the EU provides the right environment for these businesses to flourish even more. The lack of success in converting innovative achievements into commercial products or services has already been identified by the European Union as a problem that needs to be solved in order to catch up with countries such as the USA and Japan. Yet the Member Countries are still struggling to agree on something as fundamental as a harmonised Community Patent. Under the current system each Member State requires that patent applications are translated into its official language for it to be legally valid within their territory, even when an application is filed for a European Patent through the European Patent Office (EPO) in Munich. These translation costs make patenting in Europe inevitably more expensive than in competing economies

³⁰ European Association of Craft Small and Medium-sized Enterprises www.ueapme.com

and represent a significant barrier to both innovation itself and commercialisation of innovation.

The Stockholm Network appreciates that a variety of agencies have been established with the specific aim of supporting SMEs in their efforts to exploit IPRs. There is however, a need for these agencies to coordinate their efforts and make sure that the SMEs actually know that they exist. We also believe that the UK and the EU could go even further in supporting SMEs, by cutting red tape, establishing a fast track for SME patent applications and giving special treatment with regards to costs. With the support of the Treasury the UK Patent Office should also develop further the idea of mutual insurance associations for SMEs put forward by the Patent Enforcement Project Working Group in 2004.³¹

3.3 Patent Harmonisation in Europe

The efforts to put in place a Community-wide patent are not new, and neither are the controversies. The most recent attempt to revive the discussions on a Community-wide patent came in 1997, when the European Commission issued a Green Paper on the future of the patent system in Europe. The responses to the Green Paper showed a clear interest in a harmonised patent among stakeholders in Europe, which in turn encouraged the Commission to issue its proposal for a Regulation on the Community Patent in 2000.³² The proposal envisaged a Community patent, which would be granted by the European Patent Office in Munich, but applicable in every Member State. The aim was to have a Community patent available by 2001, and it was made part of the Lisbon Agenda process.

The whole idea behind a Community-wide patent was to make patent protection as easy and inexpensive to obtain and as comprehensive in its scope in the European Union as the protection granted in competing economies. By

³¹ UK Patent Office, www.patent.gov.uk

³² European Commission, www.europa.int/comm/internal_market/en/indprop/patent/ec/lisbon03-00.htm

having an affordable and efficient patent in place in Europe the competitiveness of the region will surely increase, and Europe could be on its way to becoming the leading knowledge-based economy in the world. Unfortunately, disagreement over language issues has made it impossible for the parties to reach a common ground and the work is currently stalled.

In the absence of a Community Patent, each Member State requires that patent applications are translated into its official language for it to be legally valid within their territory. This is also the case when an application is filed for a European Patent through the EPO in Munich. In order to alter this unsustainable situation, in 1999 the EPO mandated a Working Party on Cost Reduction to find ways of reducing translation related costs of patents granted by the EPO by 50%. The result was the London Agreement of 2000, which gives EPO states the possibility to waive their right under Article 65 EPC to require a full translation of an EP patent specification (including the claims) into one of that state's official languages. States with an official language in common with an EPO language (English, French and German) have to dispense with these translations requirements under the Agreement. States without an EPO language as one of their official languages can require that the claims be translated into one of their official languages.³³

Despite efforts such as the London Agreement (which has still to be ratified by all parties) the situation in Europe is unsustainable for an economy that aims to become the leading knowledge-based economy in the world. An economy based on knowledge needs an efficient, predictable and affordable patent system. This is not the case in Europe, where the costs of obtaining a patent are more than double the costs in the USA, and almost five times the costs in Japan. (A survey commissioned by the European Patent Office in 2004 found that the total cost of having a Euro-direct patent granted is on average € 24100 for a European company. By comparison, it cost € 10250 for a US company to have a

³³ The UK Patent Office
<http://www.patent.gov.uk/about/consultations/london/summary.htm#History%20of%20the%20Agreement>

USPTO patent granted and a Japanese company will pay € 5460 to receive a JPO patent.³⁴

The Stockholm Network recommends that the UK take a leading role in solving the language issues currently stalling the talks on establishing a Community-wide Patent. The first step in this direction would be to push for the London Agreement to be ratified by the necessary parties. The next step would be to actually implement an efficient, predictable and affordable Community patent.

3.4 The Computer Implemented Inventions Directive

Last year's decision by the European Parliament to reject the Council Common Position on the Computer Implemented Inventions Directive (CIID) is likely damage the climate for innovation in Europe and increase the growing innovation gap between Europe and other leading trading blocks.

In its original form, the proposed CII directive did not aim to patent software, but rather to allow the patentability of computer-based inventions. The term 'software patent', which has now become the standard jargon, is completely mistaken. Instead, the directive aimed to achieve greater harmonisation among the different patent offices with regard to the patentability of computer-implemented inventions. The European Patent Office defines a computer implemented invention as 'any invention the performance of which involves the use of a computer, computer network or other programmable apparatus and having one or more *prima facie* novel features which are realised wholly or partly by means of a computer or computer programs'. The proposed directive's four criteria for a computer implemented invention to be granted a patent - novelty, inventive step and industrial applicability - were meant to avoid a US-like situation where software *per se* is patentable.

³⁴ Roland Berger Market Research: 2004

Later drafts by the European Commission muddied the waters and threatened to turn the original aim of greater harmonisation on its head. If EU is serious about the Lisbon Agenda, Member States, EU policy makers and MEPs need to go back to the drawing board to find a solution closer to the original goals.

Without a more efficient alternative that will both reward scientific and technological innovation and ensure the rapid dissemination of existing technologies, we would be better off trying to improve the existing patent system. But for supporters of the patent system, there is no logical reason to deny the option of patentability for any type of technology, including computer implemented inventions.

The Stockholm Network believes the Computer Implemented Inventions Directive should be revived in its original form in order to support and encourage technological innovation in Europe. The UK should take the lead in this process.

3.5 The UK Approach to Multilateral and Regional Trade Agreements

In theory, there is an inherent contradiction between multilateral and regional (preferential) trading agreements. In the multilateral system, currently manifested by the World Trade Organisation (WTO), every member is obliged to grant most favored nation treatment (MFN) to all other members of the organisation when trading with one of them. This is the most basic principle of the WTO and its predecessor, the General Agreement on Tariffs and Trade (GATT). Regional trading agreements on the other hand, are preferential in nature by granting favorable terms to its signatories only. In practice, though, the two approaches go hand in hand and almost 80% of all WTO members are also involved in regional trading agreements.

In the context of intellectual property rights, the issue is addressed both on the multilateral and on the regional level. On the multilateral level IPRs are regulated

through the TRIPS Agreement. Signed in Marrakesh, (15 April 1994) as annex 1C to the Final Act establishing the WTO, the TRIPS Agreement came into effect in January 1995. It was one of the most innovative and important subjects to be included in the multilateral negotiations of the Uruguay Round. Indeed, some scholars considered TRIPS to be a revolution in international intellectual property law.

The TRIPS Agreement specifies the minimum protection standards that member countries must adopt under their domestic IP legislation. More importantly, the Agreement provides a detailed 'technical guide' for member countries with regards to the protection of IPRs. The TRIPS articles refer specifically to copyright and related rights (Art.9-14), trademarks (Art.15-21), geographical indications (Art. 22-24), industrial designs (Art. 25-27), patents (Art. 27-34), layout designs of integrated circuits (Art. 35-38) and the protection of undisclosed information, so-called data exclusivity (Art. 39).

The TRIPS framework has been criticised by various developing countries for being too one-sided and with limited prospects for the interests of their own nationals. These countries tend to emphasise the so called 'flexible' interpretation of TRIPS, in other words on the manner in which developing and least developed countries could essentially avoid or bypass the Agreement. The epitomes of this approach are the 2001 Declaration on the TRIPS Agreement and Public Health (as part of the Doha Development Agenda), and the August 2003 Agreement on the implementation of Paragraph 6 of the declaration (focusing on the manner in which least developed countries with no manufacturing capacities can import generic substitutes to existing patented pharmaceutical drugs).

But the era of TRIPS flexibilities, while celebrated in the media and by some NGOs, has proved to be the most dangerous period in the existence of the Agreement and to its future prospects. To a large extent, TRIPS flexibilities have proved to be too flexible, leading to two different yet interconnected outcomes.

The first outcome is the surge of regional and bilateral agreements led by the US and also the EU. These agreements establish IP commitments of a TRIPS+ level, which means that the parties, including developing countries, are required to implement stronger and more detailed IP provisions than those stated by TRIPS.³⁵

The second outcome is the (almost) complete stagnation in the negotiating agenda of TRIPS. In the decade that has passed, we have experienced vast and rapid technological developments, such as in the World Wide Web, mobile and digital mediums. These fields encompass highly complex and important IP issues, most of which are not covered in TRIPS.

Over the long run, the phenomena of 'TRIPS flexibilities' and 'TRIPS+' may prove incompatible with the interests of both developing and developed countries. Aside from the general economic critique of the long term utility of regional and bilateral trade agreements, their overall political legitimacy is also weaker compared with the multilateral level.

The TRIPS Agreement should therefore be strengthened and expanded in a manner that would represent the growing importance of knowledge-based factors in the global economy – both in developed and developing countries, such as India, and even China.

Significant technical assistance, as well as some concessions, should also be given to those countries that have yet to experience greater innovation and technology transfer.

³⁵ Pugatch M.P. "the International Regulation of IPRs in a TRIPs and TRIPs *plus* World", *Journal of World Investment and Trade*, vol. 6:3 (July 2005), pp. 430-465

The Stockholm Network believes that the UK should be one of the main driving forces for reviving and strengthening the TRIPS Agreement. Over the medium and long run IP-related negotiations at the multilateral level will prove far more beneficial both to developing and developed countries.

The so called 'TRIPS-flexibilities' approach, which to some extent is advocated also by the EU, should be abandoned as it contribute to nothing but the ongoing stagnation of the multilateral level and accelerates the pace of bilateral agreements. The TRIPS Agreement is a right-holders agreement and should be treated as such. Negotiations on TRIPS should aim to make the Agreement more up-to date with current technological developments, including the inclusion on new *sui generis* rights.

Undoubtedly, these negotiations should also take into account the needs of developing and least developed countries, such as in the area of technical assistance.