



Ms Victoria Whitford
IPO
Concept House
Cardiff Road
Newport
NP10 8QQ

12 August 2011

Dear Victoria

EU–India Free Trade Agreement

The IP Federation represents IP-intensive companies in the United Kingdom (see list of members attached). This includes companies which are active in India, both as local manufacturers, with research and development bases in India, and importers to India. Thus the members of the Federation, although all based in the UK, have extensive knowledge of the Indian market and patent system, as well as being contributors to the Indian economy.

We are writing to support EFPIA's [position paper](#) on this topic, dated March 2011 (copy attached), particularly as it relates to Regulatory Data Protection.

As you will be aware, Article 39.3 of the TRIPs Agreement states:

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

Since India is a member of the WTO, it must also comply with the TRIPs Agreement.

Regulatory Data Protection is a vital way to protect the investment (totalling hundreds of millions of pounds per drug) made by innovative pharmaceutical companies in clinical trials, and so to promote research into new treatments.

Allowing third parties to immediately rely on the regulatory data generated by innovators to obtain marketing authorization for a copied version of a new drug does not meet the TRIPs requirement to protect such data against unfair commercial use, in our view.

The absence of Regulatory Data Protection in India is a concern not only to the Federation's pharmaceutical members, but to members from all industrial sectors because of the bad precedent it sets of a WTO member not meeting important commitments under the TRIPs Agreement. If the EU does not seek appropriate commitments from India in the FTA to meet its TRIPs obligation in the near term, it sends entirely the wrong signal about the

The IP Federation is the operating name of the Trade Marks, Patents and Designs Federation

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importance of complying with TRIPs and will inevitably be seen as a precedent for future FTAs, whether or not the EU wishes it to be seen in that way.

Regulatory Data Protection is in the interest of innovative Indian pharmaceutical companies and the long term development of the Indian pharmaceutical industry. Therefore, we urge the UK to advocate the provision of Regulatory Data Protection in India in the EU-India trade talks as strongly as possible.

Yours sincerely

James Hayles
European Patent Attorney
President, IP Federation

c.c. John Alty, IPO
Baroness Wilcox, BIS
David Rosenberg, EFPIA
Emma Wild, CBI

IP Federation members 2011

The IP Federation (formerly TMPDF), represents the views of UK industry in both IPR policy and practice matters within the EU, the UK and internationally. Its membership comprises the innovative and influential companies listed below. It is listed on the joint Transparency Register of the European Parliament and the Commission with identity no: 83549331760-12.

ARM Ltd
AstraZeneca plc
Babcock International Ltd
BAE Systems plc
BP p.l.c.
British Telecommunications plc
British-American Tobacco Co Ltd
BTG plc
Delphi Corp.
Dyson Technology Ltd
Eli Lilly & Co Ltd
ExxonMobil Chemical Europe Inc
Ford of Europe
Fujitsu Services Ltd
GE Healthcare
GKN plc
GlaxoSmithKline plc
Hewlett-Packard Ltd
IBM UK Ltd
Infineum UK Ltd
Merck Sharp & Dohme Ltd
Microsoft Limited
Nokia UK Ltd
Nucletron Ltd
Pfizer Ltd
Philips Electronics UK Ltd
Pilkington Group Ltd
Procter & Gamble Ltd
QinetiQ Ltd
Rolls-Royce plc
Shell International Ltd
Smith & Nephew
Syngenta Ltd
The Linde Group
UCB Pharma plc
Unilever plc