

# CAMPAIGN FOR AFFORDABLE TRASTUZUMAB

Friday, November 14, 2014

To,

**Hon'ble Justice Mr. H.L. Dattu**

Hon'ble Chief Justice of India  
Supreme Court of India  
Tilak Marg New Delhi

Hon'ble Justice Smt. G. Rohini  
Chief Justice, Delhi High Court  
9, Akbar Road, New Delhi

Hon'ble Justice K.N. Basha  
Chairman  
Intellectual Property Appellate Board  
Annex-I, Guna Complex, II Floor,  
443 Anna Salai, Teynampet, Chennai

**Re: *Concerns regarding Intellectual Property Owners Association's scheduled meetings with IPAB and the Delhi High Court***

**Dear Hon'ble Justice Dattu, Hon'ble Justice Rohini and Hon'ble Justice K.N. Basha,**

We write to you on behalf of the Campaign for Affordable Trastuzumab, a network of treatment activists, patients and public interest lawyers committed to making the breast cancer drug - trastuzumab – affordable in India. We have closely followed the misuse of patent rights and more recently the vexatious litigation of the Swiss pharmaceutical company Hoffmann-La Roche Ltd in India to maintain control over the market for the life saving drug (trastuzumab), thus blocking access to treatment for many women diagnosed and suffering from HER2+ breast cancer.

This letter is to express our grave concern about the intent and purpose of the “Innovation Dialog” being organised in India from November 16-22, 2014 by the Intellectual Property Owners Association (IPOA).

The IPOA is a US-based group consisting of large corporations and law firms, looking to always interfere in intellectual property standards and enforcement in India without a balanced view about where it creates more harm than good, and where other alternatives might be better. It's especially troubling, since there are areas –such as medicines - where over-aggressive use of intellectual property have been most damaging, locking up access to affordable treatment, rather than increasing the kind of competition that drives follow on innovation forward.

Several multinational pharma corporations with interests in India are members of the IPOA.

The agenda of the IPOA event over the next two weeks includes meetings with the IPAB (a quasi-judicial body) and the Delhi High Court<sup>1</sup> and the offices of the Controller of Patents. The agenda also shows a scheduled visit to the Supreme Court of India. The intent of these meetings is clear – they are blatant attempts to influence the judicial outcomes in cases relating to drug patent disputes that are currently before the courts.

The claim that these meetings are being organised to “share experiences and perspectives on intellectual property and practice with patent practitioners and the judiciary of India” is a shameless ruse – the intent is clearly to create an opportunity for multinational pharmaceutical companies to lobby on contentious issues that are taking center stage in the struggle over the interpretation of India's medicines patent law. Among them is India's patentability

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<sup>1</sup> See [http://www.ipo.org/wp-content/uploads/2014/09/DraftAgendaIndiaTrip\\_10062014.pdf](http://www.ipo.org/wp-content/uploads/2014/09/DraftAgendaIndiaTrip_10062014.pdf)

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criteria that makes it tougher to get a patent on new forms of existing medicines; any refusal to grant excessive and unwarranted injunctions on claims of patent infringement; and discretion of the Patent Controller to grant a compulsory license to a competitor to bring down the prices of medicines that are patented.

The meetings with the IPAB and the Delhi High Court are blatant attempts to influence the judicial decisions of these institutions with regard to current and future patent disputes. We understand that IPAB will soon be hearing appeals from some IPOA member companies against the rejection of their patent applications by the Indian Patent Office.

The high courts and in particular the Delhi High Court are handling multiple litigations that demand the balancing of private IP rights with the fundamental rights to life and health enshrined in the Indian Constitution. IP owners are now increasingly using the tactic of asking for stay orders (interim injunctions) against their competitors. This is an area of growing controversy as multinational pharmaceutical companies are pushing for greater IP enforcement regardless of irreparable harm to patients.

The Patent Office is itself hearing and deciding multiple patent applications filed by corporate entities that are members of the IPOA.

You are no doubt aware that many of the members of the IPOA (notably Bristol-Myers Squibb Co, Roche Inc., Pfizer Inc. and Merck & Co)<sup>2</sup> have cases and appeals pending before the IPAB and the Delhi High Court.

CS(OS) 679/2013 [Pending in the High Court of Delhi]	BRISTOL-MYERS SQUIBB COMPANY & ANR Vs. D SHAH & ANR	Court No: 23 Next Date: 01/12/2014	Patent dispute relating to the anticancer drug dasatinib
CS(OS) 2634/2013 [Pending in the High Court of Delhi]	BRISTOL-MYERS SQUIBB COMPANY & ANR Vs. DHARMESH M SHAH & ORS	Next Date: 02/02/2015	Patent dispute relating to the anticancer drug dasatinib.
CS(OS) 1026/2009 [Pending in the High Court of Delhi]	SCHERING CORPORATION & ORS VS VIRCHOW BIOTECH (P) LTD & ANR		Patent dispute relating to the anti-HCV drug pegylated interferon alpha 2b
CS(OS) 355/2014 [Pending in the High Court of Delhi]	ROCHE PRODUCTS (INDIA) PVT LTD & ORS Vs. DRUGS CONTROLLER GENERAL OF INDIA AND ORS	Court No: 23 Last Date: 13/11/2014	Roche wants the more affordable version of the drug trastuzumab to be taken off the market on the ground that the package insert of the competitor violated their copyright.
ORA/15/2010/PT/DEL & M.P. Nos: 80 & 96 of 2012, 30 to 32 of 2013, 32 AND 33 of 2014 in ORA/15/2010/PT/DEL	MYLAN LABORATORIES LIMITED Vs. 1. PFIZER INC., 2. OSI PHARMACEUTICALS	Next Date: 27/11/2014	Patent dispute relating to the anti-cancer drug erlotinib

<sup>2</sup> See [https://www.ipo.org/imis15/Commerce/about-ipo/Corporate\\_Members/Commerce/Membership/Directories/Corporate\\_Members.aspx?hkey=8dfadb8d-c360-4022-b550-2fbb6d4ebd1](https://www.ipo.org/imis15/Commerce/about-ipo/Corporate_Members/Commerce/Membership/Directories/Corporate_Members.aspx?hkey=8dfadb8d-c360-4022-b550-2fbb6d4ebd1)

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[Pending in the IPAB]	INC., 3. THE CONTROLLER OF PATENTS 4. F. HOFFMANN-LA ROCHE LTD		
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We question the ethics and propriety of meetings and interactions between the judiciary and the IPOA delegation which consisting of representatives of pharma MNCs and the law firms that represent them in patent disputes before the IPAB and Indian courts. This has been implicitly recognised by Hon'ble Justice Dalveer Bhandari who recused himself from *Novartis AG vs. Union of India* citing his participation in two of the International Judges Conferences organised by IPOA.

At the end of the day, the stated aim of the IPOA is to function is to promote the case of of its member entities, and, is thus no more than a lobbying organization set up by corporate interests to promote their restricted view of intellectual property. It is disquieting that this lobbying organization is seeking to meet members of the judiciary in India which is hearing currently pending matters in which IPOA members are plaintiffs.

The IPOA event, providing privileged access of an IP lobby group to the highest levels of the judiciary and key quasi-judicial bodies like the IPAB, involves a serious conflict of interest and would cast a dark shadow on the neutrality of the judiciary.

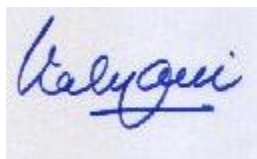
We are also proud of the standards and guidelines that have been put in place to safeguard judicial institutions from possible conflicts of interest. Our courts are in the forefront of the move to hold public institutions to account for any breach of ethics and propriety. The recent step taken by the Supreme Court to scrutinise the visitors book of the Director of Central Bureau of Investigation is a clear message in this regard, with serious note being taken of the alleged visits of individuals directly or indirectly linked to ongoing CBI investigations.

We believe that the independence of the judiciary is central to its role in protecting the right to life and health guaranteed to us by our Constitution.

We therefore request you to cancel any meetings you may have scheduled with the IPOA delegation, which is openly seeking to breach this fundamental principle of justice and thereby undermine the ethical foundations of our judicial system.

We look forward to your immediate action on this letter.

With regards,

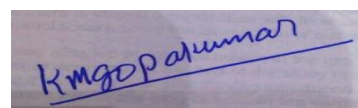


**Kalyani Menon-Sen**

*The Campaign for Affordable Trastuzumab was launched in November 2012 and endorsed at the time by over 200 Indian and global patient associations, cancer survivors, health movements, women's rights activists and eminent jurists<sup>3</sup>.*



**Leena Menghaney**



**KM Gopakumar**

<sup>3</sup> See our letter to the Indian Prime Minister [https://dontradeourlivesaway.files.wordpress.com/2013/01/letter-to-pm-on-herceptin\\_final.pdf](https://dontradeourlivesaway.files.wordpress.com/2013/01/letter-to-pm-on-herceptin_final.pdf)

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C.c.:

**Hon'ble Dr. Justice S. Murlidhar**, *The High Court of Delhi*

**Hon'ble Mr. Justice G.S. Sistani**, *The High Court of Delhi*

**Hon'ble Mr. Justice Rajiv Sahai Endlaw**, *The High Court of Delhi*

**Hon'ble Mr. Justice S. Ravindra Bhat**, *The High Court of Delhi*

**Hon'ble Mr. Justice G.P. Mittal**, *The High Court of Delhi*

**Hon'ble Mr. Justice Manmohan Singh**, *The High Court of Delhi*

**Shri Jagat Prakash Nadda**, *Hon'ble Minister for Health & Family Welfare*

**Shri. D.V. Sadananda Gowda**, *Hon'ble Minister of Law and Justice, Ministry of Law and Justice*

**Smt. Nirmala Sitaraman**, *Hon'be Minister for Commerce and Industry, **Ministry of Commerce and Industry***

**Shri P.K. Malhotra**, *Secretary, Department of Legal Affairs, Ministry of Law and Justice*

**Shri Amitabh Kant**, *Secretary, DIPP, Ministry of Commerce & Industry*

**Shri Rajeev Kher**, *Secretary, Department of Commerce, Ministry of Commerce & Industry*

**Shri Lov Verma**, *Secretary, Department of Health & Family Welfare, Ministry of Health and Family Welfare*

**Ms. Aradhana Johri**, *Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers*

**Mr. Amit Singla**, *Deputy Secretary (TPD) Department of Commerce, Ministry of Commerce & Industry*  
and Chairperson, *Parliamentary Standing Committee on Commerce*

**Mr. Sudhanshu Pandey**, *Joint Secretary, Department of Commerce, Ministry of Commerce & Industry*

**Mr. D.V. Prasad**, *Joint Secretary, DIPP, Ministry of Commerce & Industry*

**Ms. Chandni Raina**, *Director (IPR), DIPP, Ministry of Commerce & Industry*

**Dr. G.R. Raghavender**, *Director (IPR), DIPP, Ministry of Commerce & Industry*

**Mr. Chaitanya Prasad**, *Controller General of Patents, Designs & Trade Marks, DIPP, Ministry of Commerce*

**Mr. R.K. Jain**, *Additional Secretary, Department of Health & Family Welfare*

**Mr. Amal Pusp**, *Director (IH), Department of Health & Family Welfare*

**Mr. Shailendra Kumar**, *Director (Drugs), Department of Health & Family Welfare*