Campaign for Affordable Trastuzumab welcomes the dismissal of Trastuzumab’s divisionals

New Delhi, 6 August 2013: The Campaign for Affordable Trastuzumab welcomes the decision of the Patent Controller, Kolkata, to dismiss (treated as withdrawn/abandoned) the divisional applications for patents on Trastuzumab (Herceptin), the life-saving breast cancer drug controlled by Swiss pharma major Roche.

Faced with misleading statements by Roche and factually incorrect reporting by the international media, the Kolkata Patent Office took the unusual step of explaining its stand in a press release issued last evening. The note clarifies that the divisional applications (filed in 2005 and 2008) were dismissed because Genentech/Roche missed the stipulated deadline for filing of applications, and failed to appear and make their case when requested to do so by the Patent Controller.

Hailed as a major breakthrough in cancer treatment, Trastuzumab has a dramatic impact on the HER2+ variant of breast cancer, significantly reducing the risk of recurrence and expanding the possibility of a disease-free life. However, the drug is priced exorbitantly and, at Rs.9 lakhs for a minimum course of 12 injections, is out of reach for the majority of Indian women. According to official statistics, more than 25,000 Indian women (increasingly in the under-45 age group) are diagnosed with HER2+ breast cancer every year, of whom less than 5 percent are able to access Trastuzumab.

The Campaign for Affordable Trastuzumab, launched in November 2012 and endorsed by over 200 Indian and global patient associations, cancer survivors, health movements, women’s rights activists and eminent jurists - has been demanding that the Government of India intervene to enable the production of biosimilars and ensure that the drug is made available to all those who can benefit from it.

In the case of Trastuzumab, the basic compound is not patentable in India since it was developed before India revised its patent regime to make it WTO-compatible. However, in 2007, a secondary patent was granted in India to Genentech (the original developer, later acquired by Roche) on a composition of the drug. This patent is valid until 2019 and is blocking potential competitors from entering the market, faced as they are with the possibility of being slapped with a patent infringement suit by Roche. See attached factsheet for more information about the drug patent landscape.

In April this year, we alerted the Controller General of Patents to Roche’s attempt to protect its monopoly beyond the term of its patent by filing “divisional” patent applications built around matter extracted from the original “parent application”. In our letter to the Controller-General, we pointed out that these divisional applications are clearly designed to keep interested competitors from investing in the development of affordable biosimilars by creating uncertainty on the exact status of the patent protection for the drug.

India’s patent regime has been globally lauded for its ability to resist pressures from big pharma and for its stringent provisions against “evergreening” or extending the legal term of a patent by seeking fresh protection for non-significant changes in the original innovation. Moreover, Indian law does not allow the filing of divisional applications once the “parent” patent has been granted, and also clearly spells out the timeline for submitting divisional applications and for responding to queries. As we pointed out in our letter to the Controller-General, these provisions were ignored by Roche in a cynical attempt to

1 See the PIB press release at <http://pib.nic.in/newsite/erelease.aspx?relid=97629>
2 According to doctors at the Tata Memorial Cancer Centre, Mumbai.
3 Indian Patent 205534
4 See attached factsheet
subvert the legal regime and bring in "evergreening" through the back door.

Our characterisation of the divisional applications filed by Roche as frivolous and *mala fide* is borne out by the statement of the Kolkata Patent Controller, that Roche lawyers did not bother to appear for hearings and did not make written submissions despite being given repeated opportunities to make their case. The Kolkata Patent Office was therefore entirely within its rights in dismissing these applications, pending with them since 2006 and 2009.

Despite its unverified claims of having provided the drug at a reduced price to a small and select group of patients, Roche’s reaction to the decision of the Kolkata Patent Office reveals its determination to continue its predatory pricing policy even if it means subverting Indian law to reap a profit that is completely disproportionate to the cost of development and production of Trastuzumab.

The oft-repeated claim by the pharma industry, that the high prices of drugs such as Trastuzumab are justified in relation to the costs of research and development, has now been comprehensively debunked by none other than the CEO of pharma giant Glaxo Smith Kline. Calling it one of "the great myths of the industry", he revealed that the cost calculation includes the cost of failed drugs. According to him, the rate of return on R&D investment has gone up by as much as 30% in recent years because fewer drugs have flopped in late-stage testing.

Herceptin was approved by the FDA in 1998. The Genentech balance sheet shows that Herceptin brought in US$ 1.287 million for Genentech in 2007, the year that it was taken over by Roche. Since then, Herceptin has been swelling the Roche coffers – along with two other cancer drugs Avastin and Rituxan, Herceptin has accounted for 32% of Roche’s total revenue for at least five years. The money Roche has earned from Herceptin is therefore likely to be several times more than the upper figure of $800 million quoted for the cost of development. We should also take into account the hidden public funding that goes into drug development by corporates – for instance, clinical trials and supplementary research are usually carried out in hospitals and laboratories that are supported by public grants.

Recent decisions by India’s Intellectual Property Appellate Board upholding the compulsory licence for Sorafenib Tosylate and revoking the patent for Hepatitis-C drug Pegylated Interferon have dealt a major blow to big pharma’s plans to graze freely in the Indian drug market. These decisions have been applauded and welcomed by health rights groups and public interest groups around the world as an assurance of India’s political will to resist arm-twisting by pharma MNCs.

Global experience confirms that open competition via generics is a far more effective mechanism for price reduction than other options such as the negotiated price reductions being offered by the pharma industry. In May 2013, an Expert Committee set up by the Ministry of Health recommended compulsory licensing for Trastuzumab. This recommendation is still awaiting a decision from the Department of Industrial Policy and Promotion (DIPP), Ministry of Commerce.

We are concerned at reports suggesting that DIPP’s decision will depend on generic manufacturers already having applied for marketing permission for a biosimilar version of Trastuzumab. This approach is one of putting the cart before the horse – it is unlikely that generic manufacturers will

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5 http://online.wsj.com/article/SB10001424127887324635904578644100746473088.html
6 <http://dontrtradeourlivesaway.wordpress.com/2013/03/19/gsk-on-rd-and-the-1-billion-rd-myth/#more-5379>
7 <http://www.wikinvest.com/stock/Genentech_%28DNA%29>
reveal their hand by applying for marketing permission without being assured of the a clear field where patent barriers will not block their entry into the market. On the other hand, we have reason to believe that the announcement of compulsory licensing by DIPP will open the door for marketing applications from generic manufacturers who have Trastuzumab biosimilars in the pipeline.

The Campaign for Affordable Trastuzumab urges the Government of India to act without delay to allow generic manufacturers to produce biosimilars of Trastuzumab. The lives of thousands of Indian women are at stake – allowing a single predatory company to control the drug that can save them is ethically, legally and economically unjustified.

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