Compulsory licensing of patents for the cancer drug T-DM1

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- The availability of compulsory licences in relation to pharmaceutical patents has been the subject of considerable attention.
- The Indian government granted a compulsory licence to an Indian generic pharmaceutical company for Bayer's patents on the cancer drug Sorafenib (brand name Nexavar), finding Bayer's price of $65,000 per year not "reasonably affordable" in India.
- Several of the new cancer drugs are over $100,000 per year, and more recently, more than $150,000, too high for India. For the US. For Europe. For latin America. For Africa. etc...
- Some governments are showing new interest in the use of compulsory licences to curb high prices.
- Focus on one particular cancer drug: T-DM1

Why T-DM1? Why the UK?

Breast cancer is the most common cancer in women in the UK.

In 2012, 50,748 women were diagnosed with breast cancer.

Breast cancer is the second most common cause of cancer death in the UK. In 2012, 11,658 women died of breast cancer.

15-25% have HER2 positive cancers . If treated with Trastuzumab (brand name Herceptin), they have a good prognostic. But this is a first line treatment. Some patients will develop resistance.

For HER2 positive breast cancer patients at advanced stage, and who have developed resistance to Trastuzumab,T-DM1 is an important drug.

T-DM1, ado-trastuzumab emtansine in the USA & trastuzumab emtansine in Europe (trade name Kadcyla)

USA: Initial Approval: February 22, 2013. (BLA) 125427. The label has been revised twice.

Europe: Initial approval: November 19, 2013. (EMEA/H/C/2389(2013) 8149 of 15/11/2013).

> Kadcyla, as a single agent, is indicated for the treatment of adult patients with HER2-positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either: Received prior therapy for locally advanced or metastatic disease, or Developed disease recurrence during or within six months of completing adjuvant therapy.

What does Kadcyla cost?

For some patients, the price in the U.K. is £90,831 for a course of therapy.

Within in the UK, Kadcyla is only reimbursed by the Cancer Drugs Fund, in England.

The UK does not reimburse the drug in Northern Ireland, Wales or Scotland.

CL in UK

The UK Patents Act 1977 provides different grounds for the grant of compulsory licences.

One is for circumstances where it can be established that there has been an abuse of the monopoly rights in relation to such patents.

There is also a provision, Section 55, for “Use of patented inventions for services of the Crown”

Section 55 - Use of patented inventions for services of the Crown

55.-(1) Notwithstanding anything in this Act, any government department and any person authorised in writing by a government department may, for the services of the Crown and in accordance with this section, do any of the following acts in the United Kingdom in relation to a patented invention without the consent of the proprietor of the patent, that is to say -

(a) where the invention is a product, may -

(i) make, use, import or keep the product, or sell or offer to sell it where to do so would be incidental or ancillary to making, using, importing or keeping it; or

(ii) in any event, sell or offer to sell it for foreign defence purposes or for the production or supply of specified drugs and medicines, or dispose or offer to dispose of it (otherwise than by selling it) for any purpose whatever;

. . .

(c) without prejudice to the foregoing, where the invention or any product obtained directly by means of the invention is a specified drug or medicine, may sell or offer to sell the drug or medicine;

Challenges

1. UK has a conservative pro-business government, and considers the pharmaceutical industry an important domestic employer.

2. No current generic suppliers of T-DM1.

3. Roche has a decade of test data exclusivity in Europe for T-DM1.

4. Biosimilar trials are expensive.

The proposal to the UK government

1. Use the Crown Use provisions in the patent law.

2. Explore exceptions on EU regulations on test data exclusivity or UK competition laws, for excessive pricing to break the test data monopoly.

3. Ask the UK government to finance the biosimilar trials, in return for access to T-DM1 at marginal cost (or to share the costs with other governments, for the same access.)

4. Offer to manufacture biosimilar T-DM1 in the UK.

Next steps

1. Provide initial proposal to UK government in June 2015.

2. Provide MoU from one or more companies willing and able to manufacture in the UK (we have talked to three companies so far).

3. Ask government to estimate the consequences of not granting the compulsory license, on treasury and patients.

Thank you

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