Drug Information Bulletin

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Content

Editorial

Recent decision of Swiss drug major Roche to drop anti-cancer drug Herceptin patent in India is due to indirect pressure of granting compulsory licensing of Nexavar (sorafenib tosylate) to Natco last year. This decision creates easy availability of generic version of Nexavar to the millions of patients suffering from kidney and liver cancer. Bayer's product (Nexavar) costs Rs. 2.8 Laks for one month dose, where as Natco provides it at a price of Rs. 8880 for the dosage for a month and Cipla at a price of Rs.5400 for the dosage for a month.

This incidence has proved the strength of Indian Patent Act 2005, in which the definition of invention in sec. 3d prevents ever greening of patents. The other provisions like- pre and post-patent grant objection during grant of Patents, provision of compulsory licensing, provision of parallel imports are also useful instruments for improving access.

It is hoped that judicious use of the provisions of the Indian Patent Act 2005 will help to improve access to essential medicines. However there is ample scope of getting more advantage in favour of India by framing proper legislation utilizing the existing provisions of the IPR legislation.

FDA mandates warnings for Fluoroquinolones

MedPage Today reports the FDA is mandating an update to medication labels and guides for all systemic fluoroquinolones to warn of quick and potentially permanent nerve damage. The peripheral neuropathy problems seem to occur in oral or injectable variants, but not topical formulations. Unless the benefits outweigh the risks, the agency is asking doctors to switch patients to nonfluoroquinolones. Other rare but severe adverse events impacting the cardiovascular, musculoskeletal, endocrine, renal, and central nervous

systems have previously been reported with the class.

Medscape reports that around 3.8 million people received injectable versions and 23 million people received oral formulations of gemifloxacin, levofloxacin, moxifloxacin, norfloxacin, and ofloxacin in 2011. The FDA finds that nerve damage problems can exist for over a year after patients stop using fluoroquinolones.

Fluoroquinolones linked to severe Blood Sugar fluctuations in patients with Diabetes

MedPage Today reports that, according to research published online in Clinical Infectious Diseases, “fluoroquinolone antibiotics are associated with an increased risk of blood glucose swings in” patients with diabetes.

HealthDay reports that investigators looked at data on approximately 78,000 people with diabetes. The researchers found that those “who took fluoroquinolones were more likely to have severe blood sugar swings than those who took antibiotics in the other classes.” The data indicated that “the level of risk varied according to the specific fluoroquinolone.”

Swiss drug major Roche to drop anti-cancer drug Herceptin patent in India

Swiss drug major Roche has decided not to pursue its patent for anti-cancer drug Herceptin, the patent which had come up for extension till 2019, paving the way for generic drug makers to manufacture this drug.

Trastuzumab, sold under the brand name of Herceptin, is used in breast-cancer treatment and costs close to Rs 1 lakh for a month. "Roche has come to the conclusion not to pursue Indian Patent No. 205534 (the secondary patent for Trastuzumab) and the related divisional applications. This decision takes into account the strength of the particular rights and the Intellectual Property environment in India in general," a Roche spokesperson said in an email query to ET.

Roche let the patent for Herceptin lapse in May this year, however, the company had time till November to pay the fee and claim its patent.

Roche said it will continue to enforce all other patents in India and remains committed to working with the Indian government. "We believe ensuring access to innovative medicines such as Herceptin is a complex issue and that significant progress will only be made through ongoing close collaboration between the government, industry and care providers without compromising intellectual property rights or biosimilar approval requirements," it added.

Incidentally, Herceptin is the same drug which the health ministry had proposed for a compulsory licence under Section 92 of the Indian Patent Act, which allows government to revoke a patent during emergency situation. But the government had hesitated to revoke the patent because it didn't know if there were other Indian drug makers who were ready with the copy of this drug.

Herceptin contributes close to Rs 127 crore to Roche's annual turnover, according to industry estimates. Roche's decision of giving up its patent is a smart move, say IP experts as there is no Indian company manufacturing this drug due to the complex science involved. So, even after giving up the patent, Roche will be the only company that will be manufacturing this drug, band the company knows it.

"While the patent for Trastuzumab may no longer be in force, it is important to

note that there are currently no approved biosimilars of Trastuzumab in India. We support the Indian government's leadership in establishing a pathway and guidelines for the introduction of biosimilars onto the market that is based on science and is designed to ensure product quality and patient safety," said the company.
Biocon-Mylan, Reliance Life Sciences and BDR Pharma are a few companies working on a copy of Herceptin.
Multinational drug makers including Roche have come under severe pressure from the Indian government to cut the prices of key anti-cancer drugs as it is beyond the reach of a large number of the patients. Last year, the patent office issued the first ever compulsory licence to Natco Pharma to manufacture the cheaper version of German drug maker's kidney anti-cancer drug Nexavar.

Treatment of patients with Psoriasis 'Inadequate'

JAMA Dermatology study estimates extent of Nontreatment and Undertreament of Psoriasis and Psoriatic Arthritis In U.S. Patients

Nontreatment and undertreatment of patients with psoriasis and psoriatic arthritis appears to still be a significant problem in the United States, according to a study by April W. Armstrong, M.D., M.P.H., of University of California-Davis, Sacramento, and colleagues.

A total of 5,604 patients with psoriasis or psoriatic arthritis completed surveys collected by the National Psoriasis Foundation from January 2003 through December 2011.

From 2003 through 2011, patients who were untreated ranged from 36.6 percent to 49.2 percent of patients with mild psoriasis, 23.6 percent to 35.5 percent of patients with moderate psoriasis, and 9.4 percent to 29.7 percent of patients with severe psoriasis. Among those receiving treatment, 29.5 percent of patients with moderate psoriasis and 21.5 percent of patients with severe psoriasis were treated with topical agents alone. Although adverse effects and a lack of effectiveness were primary reasons for discontinuing biological agents, the inability to obtain adequate insurance coverage was among the top reasons for discontinuation. Overall, 52.3 percent of patients with psoriasis and 45.5 percent of patients with psoriatic arthritis were dissatisfied with their treatment, according to study results.

“While various treatment modalities are available for psoriasis and psoriatic arthritis, widespread treatment dissatisfaction exists. Efforts in advocacy and education are necessary to ensure that effective treatments are accessible to this patient population,” the authors conclude.

Ref. JAMA Dermatol. Published August 14, 2013

India spurns cancer patients: Nation seeks to cap high cost of drugs to treat non-infectious diseases.

Once the scourge of the developing world, infectious diseases such as malaria, tuberculosis and AIDS can now be fought with cheap drugs. But as people in poorer nations live longer and adopt Western habits, non-communicable diseases such as heart disease, diabetes and cancer have become the main killers — and paying for their treatment has become a thorny problem.
India may now be drawing a line in the sand. In the past three weeks, officials there have refused patents on two breast cancer drugs — the latest in a series of

decisions to limit patents on pricey brand-name medications. These moves reflect a tension: India now surpasses the United States in terms of annual cancer deaths, and wants to find ways to treat the disease cheaply. But this desire runs counter to the goals of drug makers, who see middle-income nations as central to their growth plans.

The first of the recent rejections occurred on 27 July, when an Indian federal board of patent officials revoked a patent on a slightly modified version of the breast cancer drug lapatinib, sold as Tykerb by London-based pharmaceutical firm GlaxoSmithKline. Then, on 4 August, Swiss drug company Roche reported that a patent office in the city of Kolkata, a hub of the national patent system, would not grant patents on a version of the company's drug trastuzumab, sold as Herceptin. Indian officials allowed other patents that will protect both drugs from generic competition until 2019. But the rulings will stop the companies from extending their patent protection beyond that date, opening a window for manufacturers of generic drugs to then step in.

The fight echoes one in the late 1990s and early 2000s over drugs for treating infections such as HIV. That dispute was largely resolved when drug makers allowed developing-world companies to create cheap generic medicines. Today, antiretroviral treatments can be bought for less than US$100 a year, compared with more than $10,000 a year in 2000, according to international aid organization Doctors Without Borders (Médecins Sans Frontières), based in Geneva, Switzerland.

For details:
http://www.nature.com/news/india-spurns-cancer-patents-1.13552
Ref. Nature 500, 266 (15 August 2013)

Forthcoming Event

Drug Awareness Programme amongst School Students
24th August 2013
Vidyasagar Vidyapith, Kolkata

Jointly organized by:
IPA Bengal Pharma & Health Care Trust
&
Diabetes Awareness & You

Reader's Column

Dear Dr. Mandal,

That article on "Doctors in India defy guidelines on generic drugs", was quite good – it was relevant to everybody who reads The Drug Information Bulletin.

However I did not see one suggestion which would have been a reasonable compromise. If the prescription is written by generic name with the brand name within brackets, that would fulfill the criteria of the generic name as well as show the preference of the prescriber for the brand name. This is what is being taught and insist upon in Sri Lanka, where a doctor may say I must to what I believe is the best for the patient. By the way in Sri Lanka the law is blind towards generic substitution – it neither allows it nor prevents it.

However there is a very subtle element of "patient empowerment" here - the patient gets to know the generic name and can therefore compare what is available on the market. In that way, it is the patient will ultimately decides. You would have of course have the phrase "If the One Who Decides Does Not Pay, and the One Who Pays Does Not Decide, Can Proper Market Forces Operate?." A cynic (also the massive pharmaceutical promotion aimed at the prescriber) added the postscript of "… and the one who decides is often paid…".

Regards.

Dr. J. De Silva
Sri Lanka