NEWS IN BRIEF

PATENTLY JUSTIFIABLE

The Supreme Court of India has rejected the patent petition by Novartis for its blockbuster drug Gleevec used in chronic myeloid leukemia (CML). To understand the significance of this landmark verdict we need to relook at the Patent law in India. In the original Indian Patents Act 1970 there was no product patent system for pharmaceuticals, the term of the process patent was 7 years and the royalty ceiling was 4% of the ex-factory sale price. So Indian drug manufacturers could produce drugs using different processes and India became one of the leading global suppliers of bulk drugs and generic formulations. However as member of the World Trade Organization (WTO), India had to toe the line with the agreement on TRIPS (Trade Related Intellectual Property Rights) and modify its patent laws in 2005. So product patents were introduced for drugs, the term of protection for product patents became 20 years, and there was now no royalty ceiling for licenses. However section 3(d) of the amended act clearly states that patent will not be awarded to the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance. The drug in question Imatinib was patented in 1996. In 2006 Novartis applied for a patent for its beta crystalline form Imatinib mesylate claiming better absorption. The patent office rejected the company's patent application because it was not a new medicine but an amended version of its earlier product a technique dubbed as "evergreening". Officials also turned down a subsequent appeal by the company three years later. Novartis then approached the Supreme Court arguing that certain properties of the drug counted as improved efficacy but the Court did not agree, stating that improved therapeutic efficacy must be documented both in the laboratory and in clinical trials. Since Novartis had trials only based on the original model of the drug its claim was dismissed.

Novartis sells Gleevec at Rs 4115/tablet amounting to an annual cost of Rs 15 lakh /patient. The Indian company Resonance sells the same tablet for Rs 30/ tablet coming to an annual cost of Rs 10,000/-. If Novartis had won, Indian generic companies would have had to stop production and many patients would no longer be able to afford treatment. No wonder this Supreme Court judgment is being widely celebrated by health activists and patient forums (*The Hindu 7 April 2013*).

THE NEW DEADLY FLU

It is named H7N9. As of 9th April, 24 cases, 8 deaths from 11 cities in Eastern China are reported. It seems difficult to predict whether it will rapidly fizzle out, just settle down in an animal reservoir or evolve into a deadly pandemic. It appears to have jumped from birds to humans since the H7N9 virus has been found in chickens, pigeons and ducks in live bird markets in Shanghai and Hangzhou — making markets the leading suspected source. Unlike its cousin H5N1 — which has killed millions of birds and several hundred people in Asia and elsewhere since 2003 — H7N9 does not cause serious bird disease, greatly complicating efforts to control it. It would be next to impossible to detect H7N9 through routine surveillance. This means stopping animal-to-human transmission is impossible (*Nature 9 April 2013*).

MILTEFOSINE FOR KALA-AZAR

Sodium stibogluconate has a failure rate of almost 65% in Kala-azar, in Bihar. In the last decade oral miltefosine has emerged as a useful alternative. Reports from Nepal show that this joy may be short-lived. In a recent study published in Clinical Infectious Diseases, of 120 patients treated with miltefosine in Nepal, 10% relapsed by 6 months and 20% by 1 year. Cure rates dropped from 82.5% six months after treatment to 73.3% after 12 months. Relapse was most common in children under 12 years old. A similar failure rate of 7% was reported from Banaras Hindu University last year. In 2010, the WHO's expert committee on leishmaniasis had "strongly recommended not to use miltefosine monotherapy" (*Nature 8 March 2013*).

SYNTHETIC VACCINES

Scientists have used computer simulations to create a model of the protein shell of the virus which causes hand foot and mouth disease. They then reconstructed it from synthetic protein components. This was used to develop a vaccine which was entirely free from genetic material. This synthetic vaccine has the added advantage of absolutely no genetic material. This may have implications for the development of new polio vaccines. The hand foot and mouth virus is similar to the polio virus with both possessing a peculiar icosahedral structure. This polyhedron with 20 triangular faces has a tendency to fall apart at the edges during transport and dissemination. In this new synthetic vaccine, strong disulfide bonds were created to circumvent this. What this translates to is that the vaccine will not require cold storage and will be easier to produce and distribute. (*Nature 28 March 2013*).

Gouri Rao Passi
gouripassi@hotmail.com