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On August 6, 2007, the Madras High Court in India dismissed Novartis' challenge to an Indian law that does not allow patents for minor modifications to known compounds. Charities campaigning to increase access to medicines welcome the decision. "This ruling gives the clear guidance needed for the Indian patent offices to assess the thousands of drug patent applications pending before them", says Ellen t'Hoen of Médecins Sans Frontières.

The base compound at the centre of this legal battle, imatinib, was patented worldwide in 1993. India had no patent protection for drugs until the Indian Patents Act 2005, which allows patents for compounds that represent new inventions since 1995. Thus Indian companies can make generic versions of imatinib by engineering slight modifications to the molecule that might not be considered to be a new invention.

In January, 2006, the Indian Patent Office disallowed a patent for Novartis' Glivec (imatinib) because it did not satisfy the requirements of Section 3(d) of the Indian Patents Act 2005—this section denies patents on the basis of trivial modifications of existing compounds (known as 'evergreening').

In August, 2006, Novartis challenged this decision in the Madras High Court and asked it to declare Section 3(d) unconstitutional and in breach of India's obligation under the Trade-related Aspects of Intellectual Property Rights agreement. The court ruled that it had no jurisdiction on whether Indian patent laws were complying with rules set by the World Trade Organisation.

Carrie Scott from Novartis says, "there are inadequacies in Indian patent law that will have long-term consequences for patients. India's patent system [needs to be] strengthened so that incentives are in place to bring patients...new and better medicines".

According to Brian Druker (Oregon Health and Science University Cancer Institute, Portland, OR, USA), "the most important issue is access to drugs at affordable prices. Novartis would argue that they already provide free [imatinib] to 7000 patients in India through the Glivec International Patient Assistance Program. While this is to be commended, I estimate this covers less than 5% of patients in India who need the drug". However, he adds that as India's pharmaceutical industry expands and seeks to export its products abroad it might fall foul of it's own rules, "if patents can be circumvented by slight modifications as occurred here, it would mean that a drug generated by an Indian company would be subject to the same erosion of market share by other companies".

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New treatment combination for testicular cancer

High-dose chemotherapy with carboplatin and etoposide followed by haemopoietic rescue with peripheral-blood stem-cell transplantation (PBSCT) is effective in recurrent testicular cancer (*N Engl J Med* 2007; **357:** 340–48).

"Switching to PBSCT [from bone marrow transplantation] reduced cost, converted [the procedure] to outpatient therapy, and allowed rapid haematological engraftment, allowing the second course of high-dose chemotherapy to be given just 3–4 weeks after the first course", says author Lawrence Einhorn (Indiana University, Bloomington, IN, USA).

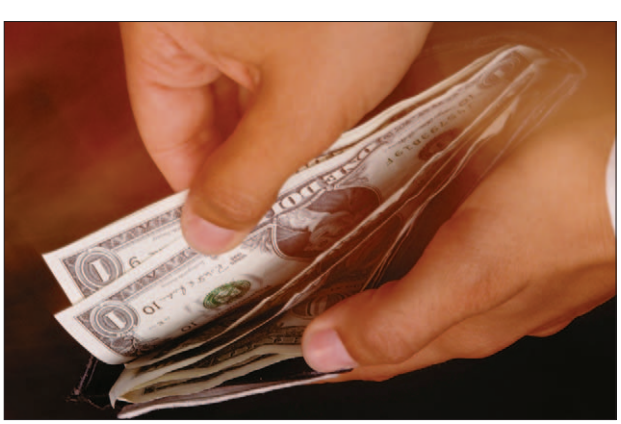
The researchers analysed records from 184 patients with metastatic germ-cell tumours, who relapsed after receiving cisplatin-containing chemotherapy. 173 patients had received two courses of high-dose carboplatin (700 mg/m^2) and etoposide (750 mg/m^2) for 3 days, each followed by an infusion of stem cells. 11 patients received one course.

116 patients had complete remission (median follow-up=48 months, range 14–118). 104 patients showed remission beyond 2 years. Remission was higher with high-dose chemotherapy used as second-line compared with third-line chemotherapy.

"Since the potential to cure patients after they fail standard therapy without transplant is limited, the results offer hope in this young population of patients", says Manish Kohli (University of Rochester Medical Center, NY, USA)

"The report excludes the highest-risk patients with mediastinal primaries and cisplatin-refractory tumours", says Guru Sonpavde (US Oncology Research, Houston, TX, USA). "Studies in the past have shown durable response in this group with paclitaxel incorporated chemotherapy." He continues, "conventional chemotherapy (paclitaxel, ifosfamide, cisplatin) has outcomes comparable to transplantation in relapsed patients with good risk. Therefore, the necessity of transplantation in a good risk population can only be answered with randomised trials".

Kaushal Raj Pandey



Peripheral-blood stem-cell transplantation reduces costs