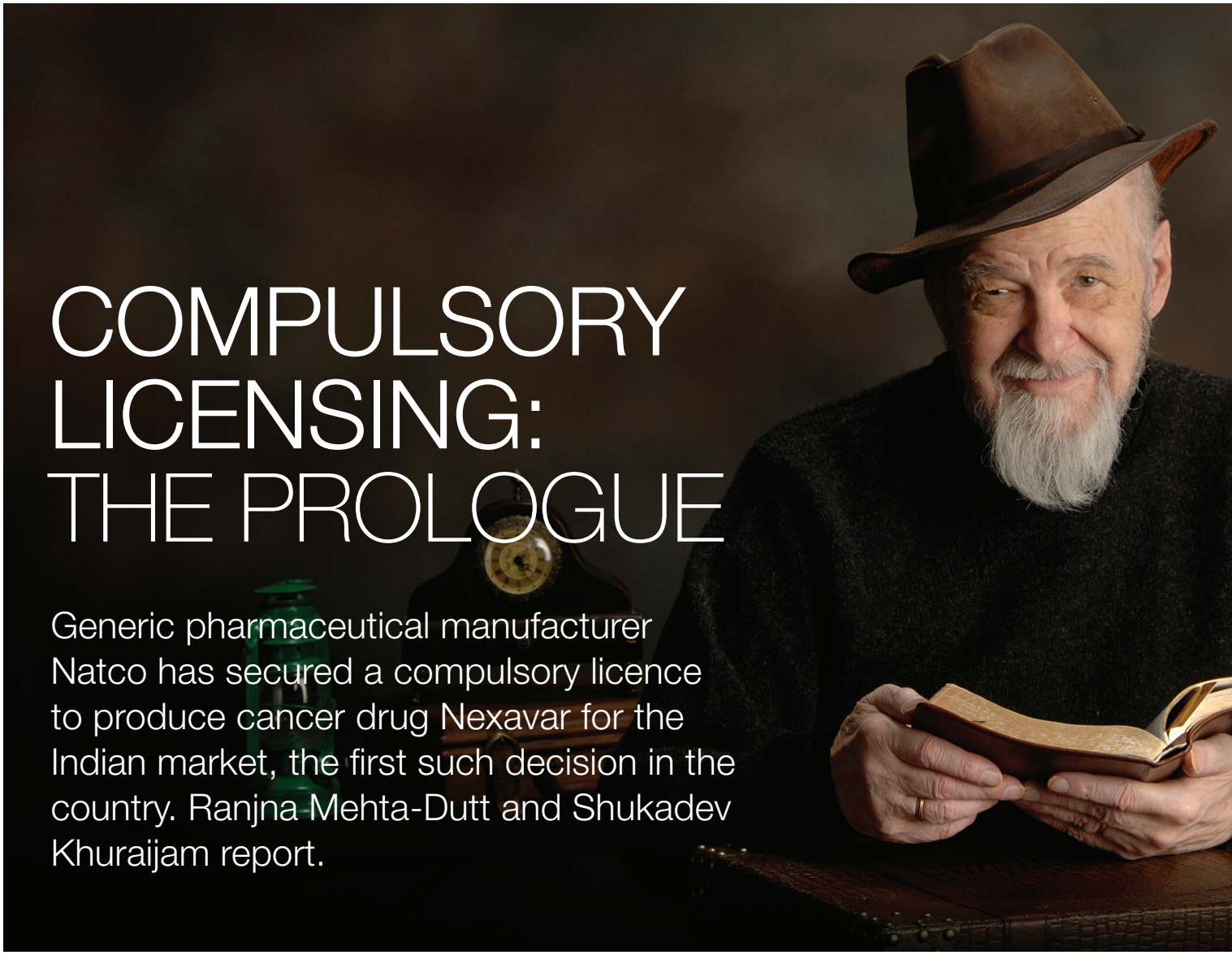

COMPULSORY LICENSING: THE PROLOGUE

Generic pharmaceutical manufacturer Natco has secured a compulsory licence to produce cancer drug Nexavar for the Indian market, the first such decision in the country. Ranjna Mehta-Dutt and Shukadev Khuraijam report.

"The beginning is easy; what happens next is much harder"—Anonymous

Against the backdrop of an illusory Indian spring, the Indian patent office bequeathed India's first compulsory licence to a local generic drug manufacturer: Natco Pharma. In doing so, it placed into practical circulation an untested provision—one it, apparently, considered perfect on paper. Germany's Bayer, which had been granted the patent in question for its liver/kidney cancer drug Nexavar, has so far kept its future intention on the matter under wraps. The decision was issued by PH Kurian on his last day in office as the controller general of patents, designs and trademarks. Having essayed many groundbreaking transformations at the patent office during his tenure, he can be said to have 'gone out with a bang' after seemingly opening the flood gates with this unprecedented ruling.

Before the conclusive hearings which spawned the order, Bayer fought a pitched battle with its entire arsenal to frustrate Natco's assault. Commencing with filing of petitions requesting stay of the compulsory licence proceedings before the patent office, Bayer pressed forward by subsequently filing writ petitions before the High Courts of Bombay and Delhi. These writ petitions challenged the controller's initial order recording a *prima facie* finding of the matter being an appropriate case for grant of a compulsory licence. Bayer was ultimately given the liberty to raise all pleas against the *prima facie* finding in the compulsory licence proceedings before the patent office.

Despite Bayer's strong protestations during several protracted hearings, the patent office granted the compulsory licence to Natco upholding all three grounds taken by it, namely: inadequate supply of the drug; unaffordable pricing; and non-working of the patented drug in India.

The order stated that Bayer's supply of Nexavar to merely 2 percent of the patient population of India does not meet the "reasonable requirements of the public". In coming to this conclusion, the patent office mainly relied on the 'statements of working' filed by Bayer for three calendar years post grant of its patent. In the opinion of the patent office, these statements showed importation of an inadequate amount of Nexavar *vis-à-vis* the patient population. Also, the patent office refused to accept Bayer's contention that sales made by Cipla (an alleged infringer) should be taken into account in deciding this issue.

On the issue of affordability, Bayer's pricing of the drug at approximately INR 280,000 (US $5,700) for a month's dose was judged to be extremely high by the patent office, leading it to observe that the "drug was not bought by the public due to the fact that the price was not reasonably affordable to them". Bayer countered that R&D cost in drug discovery is enormous, that more investments are required for future innovations and that affordability to the public should be construed with respect to different

sections/classes of the society. These arguments gained notional acceptance with the patent office but failed to secure a ruling in Bayer's favour.

Significantly, it was also held that mere importation of Bayer's drug into India did not amount to 'working' as envisaged under the Patents Act 1970. While it appears that Natco did not strictly plead that importation cannot amount to working, the patent office in its order assiduously referred to the Paris Convention, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and various provisions in the Indian patent statute to arrive at the conclusion that 'working' cannot mean importation, and that the phrase 'worked in the territory of India' means 'manufactured to a reasonable extent in India'.

For its part, Natco has been enjoined, *inter alia:* to pay Bayer a royalty calculated at 6 percent on its net sales each quarter *re* the licensed drug; to cap the price for its medicine at INR 8,800 (approximately US $185) for a month's dose of 120 tablets; and to distribute its drug free of charge to at least 600 disadvantaged patients each year. All the while Natco is to ensure that its product is distinct from Bayer's drug in the market and that production is restricted to its own manufacturing facilities (with no window for outsourcing or importation, etc). Bayer, in turn, has been afforded the liberty to grant licences to third parties.

In the present circumstances, inconceivable though it may be that Natco would fritter away this unprecedented compulsory licence, Bayer may do well to ensure that its patent is indeed worked, as another two years of non-working will give rise to the threat of revocation actions being filed by any interested party.

The patent office's order is appealable before the Intellectual Property Appellate Board. Whether Bayer will exercise this option remains to be seen, primarily in the context of the patent office upholding all three grounds argued by Natco.

India fulfilled its TRIPS obligations in 2005 by allowing product patents in all fields of technology. However, there were many challenges after the dawn of the product patent regime. With the statute containing provisions for compulsory licensing, the test of these provisions with respect to pharmaceutical patents in India was a story waiting to unfold. The message for patent holders, especially pharma patent holders, cannot be clearer: availability and affordability of the drug are vital to maintaining and safeguarding patent rights.

On the issue of price, the concept of differential pricing may be adopted so that the question of affordability does not arise. In the wake of this order, in what may be interpreted as a pre-emptive measure, Roche has announced price cuts for two of its cancer drugs in India: Herceptin and Mabthera.

As regards the ruling that importation does not amount to working of a patent in India, this aspect raises more questions than it answers, especially in light of patents in other areas.

With the prologue in place, the tale will continue. ■

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"THE PATENT OFFICE ARRIVED AT THE CONCLUSION THAT 'WORKING' CANNOT MEAN IMPORTATION, AND THAT THE PHRASE 'WORKED IN THE TERRITORY OF INDIA' MEANS 'MANUFACTURED TO A REASONABLE EXTENT IN INDIA'."

Ranjna Mehta-Dutt has practised in the field of IP rights for 15 years. She has vast experience in drafting patent specifications and handling patent applications in diverse fields of technology including chemistry, biotechnology and pharmaceuticals. Mehta-Dutt is an expert at prosecuting designs applications and handling patent/designs oppositions.

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