PATENT WATCH

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NIH denies march-in rights on Norvir patent

The US National Institutes of Health (NIH) has refused to override AbbVie's patents on the HIV drug Norvir (ritonavir) under so-called march-in rights. The decision means that the cost of Norvir in the United States will remain higher than in several other high-income countries.

March-in rights are a provision of US patent legislation that allows the NIH to 'march in' — under very limited circumstances — and topple a patentee's exclusivity to ensure that government-funded inventions are available to the public. Research by AbbVie's predecessor Abbott that led to some of Norvir's patents had been partly funded by NIH grants from an initiative in the 1980s to develop more effective AIDS drugs.

March-in rights can be granted if there has been insufficient practical application of the invention or if the health and safety needs of the public have not been satisfied. Four groups (the American Medical Students Association, Knowledge Ecology International, U.S. Public Interest Research Group and the Universities Allied for Essential Medicines) challenged the patents on these grounds. They asserted that practical application had not been achieved because of high price differences between the United states (which uses private sector health-care insurance schemes) and other high-income countries that have government-funded health care. For example, Norvir costs just over US$9 per tablet in the United States but only US$1 in the United Kingdom. And the four groups said that this differential pricing was having an adverse effect on public health.

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But the NIH said the availability and use of Norvir around the world showed that AbbVie had achieved practical application of the invention. It also noted that the cost of Norvir had not changed in almost 10 years, and that AbbVie provides assisted access to the drug for eligible patients.

Norvir is an HIV protease inhibitor that has been on the US market since 1995 and is used in combination with antiviral agents to boost the efficacy of the treatment regimen. It is also in clinical trials (as an efficacy-enhancing agent) for the therapy of hepatitis C virus infection.

The challengers also wanted the NIH to establish new rules related more generally to patents and drug pricing — namely, that if the cost of a drug in the United States was determined to be higher than a threshold value, based on prices in other high-income countries, then a licence to produce lower-cost copies should be granted. Here the NIH said this would not be appropriate, because the US health-care system is not comparable to those in other counties. "The extraordinary remedy of march-in is not an appropriate means of controlling prices of drugs," concluded the NIH.

Any future petitioners for march-in rights face an uphill struggle. Since the provision was enacted 33 years ago — as part of the Bayh-Dole act, which aimed to stimulate the commercialization of government-funded inventions — there have been only five petitions, none of which has been successful.

However, all is not safe for AbbVie, as the validity of Norvir's patents is currently subject to challenges by several generics manufacturers. A total of 17 patents protect Norvir and its different formulations and combination use, with different expiration dates ranging from 2013 to 2025. In the absence of a successful challenge, the NIH noted that the earliest likely approval for a generic would be at the end of 2016.

NIH decision: http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf

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