Patents on Ritonavir, the August 16, 2011 WIPO Study

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A few days ago, I posted a link to a KEI blog about "USPTO issued patents mentioning ritonavir in the patent claim." <u>http://www.keionline.org/node/1297</u>. I have since expanded the KEI blog entry, for example, by identifying 42 patents connected to the NIH contract that led to the development of ritonavir, and the 11 additional patents with Bayh-Dole Act rights associated with them.

In my blog I simply looked at the 236 patents that either cited ritonivir in the patent clams (194) or that mentioned the NIH contract (42). Esteban Burrone subcalled my attention to the August 16, 2011 WIPO study on the patent landscape by Landon IP, which is available here:

http://www.wipo.int/patentscope/en/programs/patent_landscapes/reports/ritonavir.html. According to the WIPO/Landon study:

"There have been over 800 patents filed since the initial PCT application WO1994014436 to protect different aspects of Ritonavir and its methods of use. A large number of documents filed subsequent to the initial application still protect the structure of Ritonavir as described in the initial application. As one would suspect, subsequent patent filings continue to narrow the focus of protection of Ritonavir by incorporating novel aspects to the subject of Ritonavir. The implications of patent protection are important for developing countries to consider. Simply licensing the initial key documents will not provide adequate freedom to operate because of the breadth of coverage by subsequent patents."

There are all sorts of policy and health ramifications associated with the proliferation of patents on ritionavir, including of course, a deeper appreciation for why it is important that countries reject efforts in trade agreements to shrink national flexibility on standards for granting patents. Many of these patents do not meet the higher standards for granting pharmaceutical patents in India, for example, but do qualify in many other countries, both developed and developing. This is a topic that will be discussed in the TPPA negotiations this

month in Peru, where President Obama and USTR will push their proposal to mandate granting more patents, including by imposing this new obligation on TPPA member countries such as Vietnam, Peru, Thailand, Malaysia, and Chile:

"In addition, the Parties confirm that: patents shall be available for any new forms, uses, or methods of using a known product; and a new form, use, or method of using a known product may satisfy the criteria for patentability, even if such invention does not result in the enhancement of the known efficacy of that product."

The WIPO study also sheds some light on the potential benefits of the Medicines Patent Pool licenses for patents on cobicistat, a new Gilead drug that is expected to offer similar benefits to ritonavir.

These are the 805 patents that WIPO says "protect different aspects of Ritonavir and its methods of use."

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