

PUBLIC PATENT FOUNDATION

Representing the Public's Interests in the Patent System

PUBPAT

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Dr. Mark Rohrbaugh
Director of the Office of Technology Transfer
Office of Intramural Research
National Institutes of Health
6011 Executive Blvd., Suite 325
Rockville, MD 20852

Re: Analysis of Patents Relevant to the Ritonavir Petition

Dear Dr. Rohrbaugh:

As Executive Director of the Public Patent Foundation ("PUBPAT"), a not-for-profit legal services organization working to protect the public from the harms caused by wrongly issued patents and unsound patent policy, I write to provide patent related information and analysis pertinent to Essential Inventions' Petition to Promote Access to Ritonavir ("Ritonavir Petition").

By way of introduction, I am a registered patent attorney with extensive experience litigating, licensing, prosecuting, and otherwise counseling clients with respect to patents. Prior to founding PUBPAT, I practiced patent law with Skadden, Arps, Slate, Meagher & Flom, LLP, Brobeck, Phleger & Harrison, LLP, and Patterson, Belknap, Webb & Tyler, LLP, all in New York, and served the Honorable Randall R. Rader, Circuit Judge for the U.S. Court of Appeals for the Federal Circuit in Washington, D.C. A substantial segment of my experience has focused on pharmaceutical patent issues, including the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act") and the role of the Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations publication ("Orange Book"). In addition to litigating several generic pharmaceutical patent infringement cases, otherwise called ANDA cases, I have also comprehensively evaluated the patent portfolios of pharmaceutical companies and issued opinions regarding the scope and validity of specific pharmaceutical patents.

PUBPAT has undertaken a review of the patents pertaining to Abbott Laboratories' ritonavir drug products. In total, there are 5 patents listed by Abbott in the Orange Book for its approved ritonavir capsule product. Of those 5, the Ritonavir Petition would, if granted, provide access to 4, leaving only one patent, U.S. Patent No. 6,232,333 ("333 patent"), as a potential barrier to making an effective generic ritonavir capsule product. Table 1 below sets forth the Orange Book patent listing for Abbott's ritonavir capsule product and also indicates which of those patents are subject to the Ritonavir Petition.

<u>Patent No.</u>	<u>Listed for Abbott's Ritonavir Capsule</u>	<u>Subject to the Ritonavir Petition</u>
5,541,206	Yes	Yes
5,635,523	Yes	Yes
5,648,497	Yes	Yes
5,846,987	Yes	Yes
6,232,333	Yes	No

Table 1: Orange Book Listed Patents for Abbott's Ritonavir Capsule

The '333 patent, unlike each of the other 4 patents listed for Abbott's ritonavir capsule, does not claim the active ingredient, ritonavir, itself. Rather, it merely claims a pharmaceutical composition containing ritonavir. Upon initial review, we have serious doubts about the validity of the '333 patent and its applicability to an effective generic ritonavir product. One issue regarding the '333 patent's validity is that its Abstract and Specification purport to teach an invention providing "improved bioavailability." Yet, no such limitation is present in any of the '333 patent's claims. Such a missing limitation means that the scope of the claims is much broader than what the patent otherwise purports to cover. This breadth of the claims increases the likelihood that they are invalid.

Regardless, the existence of the '333 patent in no way detracts from the importance or utility of the Ritonavir Petition. Access to the technology claimed in the 4 other patents that pertain to ritonavir is absolutely necessary to making an effective ritonavir capsule product available to the American public on fair terms. Further, a potential producer of a generic ritonavir product is much more likely to challenge the '333 patent if it stands alone as the sole patent at issue than if the other 4 patents must also be dealt with. This is especially true since the '333 patent has such glaring validity issues and may be much more easily designed around than the other 4 patents since it does not cover the active ingredient ritonavir itself.

In conclusion, there is absolutely no patent related reason to quell support of the Ritonavir Petition. If PUBPAT can be of any further assistance with respect to this matter, please do not hesitate to contact me.

Sincerely,



Dan Ravicher

cc: James Love
Essential Inventions, Inc.