15 December 2011

Robert Weismann and Peter Maybarduk  
Public Citizen  
1600 20th Street NW  
Washington, D.C. 20009  
(202) 588-1000  

RE: Your letter of November 7th, 2011

Dear Mr. Weismann and Mr. Maybarduk,

Thank you for your letter concerning the intention of Johnson & Johnson to announce its decision to formally enter negotiations with the Medicines Patent Pool to license the company’s patents and related data to the Pool.

We believe that voluntary licensing is an ideal mechanism by which to expand access and reduce prices to HIV drugs. To that end, during 2011 we have completed five new license agreements with generic manufacturers for our newest HIV medicine rilpivirine. The geographic scope of our access efforts now spans 112 low- and middle-income countries. In addition we have expanded a number of our existing voluntary licensing agreements as well as our agreement with Gilead for the development of a once-daily fixed dose combination of EDURANT® (rilpivirine) and Gilead’s Truvada® (emtricitabine 200 mg/tenofovir 300 mg). We will continue to build on and enhance our generic licensing agreements.

As a company policy, we do not disclose or discuss the details of our licensing agreements. For your information, I’ve attached a recent update that we shared on our access efforts and agreements.

We support the MPP Foundation in their initiative to expand voluntary licensing and are arranging for a meeting with them during which we will share the outcome of our evaluation process. After we have met with them, we will certainly make ourselves available to meet with your team to provide any further clarification and answer your questions.

With best regards,

Will Stephens  
VP Global Access and Partnerships Program, Janssen Global Services Inc  

Sent on behalf of William C. Weldon
Global Access and Partnerships Program

The Janssen Global Access & Partnerships Program (GAPP) team is delighted to share some of the exciting results of our recent efforts to ensure that HIV patients worldwide have sustainable and affordable access to our HIV medicines today.

Our licensing agreements with generic manufacturers in South Africa and India are key to providing access to our HIV drugs. Together, these agreements are making a difference. Importantly, they go beyond simply securing our intellectual property. We require our generic partners to meet the essential operational requirements of effective HIV drug supply, such as: securing timely In-country registrations; ensuring and/or improving supply chain; securing quality drug products; and monitoring the safety and effectiveness of our products. Medical, ethical and social values underpin our access program. In support of these efforts, we collaborate with our generic partners to address product awareness and/or information needs. We continue to build on and enhance our generic licensing agreements, recent developments include:

- **PREXIVON® (dolutegravir)**: In keeping with our commitment to affordability, we have reduced the total access price of PREXIVON® in South Africa in 2013. In solidarity with our local partners, we have also reduced the price of the drug's active ingredient, dolutegravir, by 20% in South Africa.
- **AIDS ARVs (amprenavir, lopinavir, nelfinavir)**: We have also been able to reach agreements with generic manufacturers in India, China and other countries to provide access to these critical ARVs.

**Gilead Agreement for FDC of EDURANT® and Truvada®**

In July, we expanded our original agreement with Gilead Sciences, Inc. to develop a once-daily FDC of EDURANT® and Truvada® for patients who are newly initiating ART or who require a change in ART regimen. This agreement will enable us to supply EDURANT® and Truvada® in combination, which can simplify the treatment regimen for patients.

**Registrations in Sub-Saharan Africa**

We have made good progress with regulatory approvals for EDURANT® (tenofovir DF and emtricitabine) in 22 countries, reflecting the regional commitment to stopping HIV. These countries include Kenya, Tanzania, South Africa, and Nigeria, among others. Our program now covers 112 countries in Sub-Saharan Africa.

**Broadening the Geographic Scope of Access**

We are committed to reaching more of those in need of our HIV medicines in resource-limited countries. We are pleased to announce that we are now working to identify the potential for extending our Program to more countries. These efforts are ongoing, and we are in the process of increasing our Program’s geographic scope from 63 to 122 countries for EDURANT® (tenofovir DF and emtricitabine).

**Our Program now covers countries home to 82% of people living with HIV worldwide.**

**Treatment Optimization**

Today, first-line treatment remains the priority in many resource-limited countries, however PREZIDEX® and INTENSA® are currently indicated for treatment-experienced patients and are indicated for those patients in need of intensified treatment.

However, interest is growing in the potential application of dolutegravir as second-line therapy. Dolutegravir is currently indicated for use in the setting of treatment failure or virologic failure in resource-limited settings. This belief that it is a drug of choice in resource-limited settings is based on the latest data showing that dolutegravir is a safe and effective treatment option, and is well tolerated.

We continue to build on our comprehensive access strategy for our HIV medicines in resource-limited settings and look forward to sharing additional initiatives in the future. As always, please don’t hesitate to contact us if you have any questions.

Wally Stabb
Vice President, Global Access & Partnerships
Janssen Global Services, LLC