Health Action International Commentary

Johnson & Johnson rejection of the Medicines Patent Pool: what will the ATMi say now?

The Medicines Patent Pool (MPP) has the potential to have a life-changing effect on access to treatment for people living with HIV/AIDS, particularly in poor countries. But, for the Patent Pool to succeed, originator companies need to licence their HIV/AIDS medicine patents to the Pool in order that generic treatments can be licensed and manufactured at a fraction of the cost of the brand name products.

The current edition of the Access to Medicines index (ATMi 2010), a Dutch foundation that ranks transnational pharmaceutical companies on their contribution to global access to medicines, rated Johnson & Johnson (J&J) as ninth (out of twenty) most corporately responsible company in terms of Access to Medicines. Indeed, this high rank in 2010 was in part due to its engagement with the Patent Pool, with the index singling them out for praise as 'industry Best Practice for Patent Pool dialogue'. A model, then, of socially responsible licensing and engagement with an innovative tool to increase access to medicines in resource poor settings, aimed at helping the people in the world living with HIV/AIDS.

But something went wrong in December of last year, whilst the ATMi was still current, when J&J announced it would not be joining the MPP and walked away from negotiations. This is a huge disappointment and blow for the global Access to Medicines movement. Moreover, for a company heralded as displaying best practice, J&J has now set an extremely poor example to other companies currently negotiating their patents with the MPP. J&J's engagement with the ATMi to demonstrate its commitment to corporate social responsibility contrasts strongly with the corporate social irresponsibility displayed by walking away from the MPP. It is expected that this will undoubtedly have implications for their next ranking in the ATMi due to be published in a few months' time.

Against a background of vehement criticism of both the MPP and pharmaceutical company Gilead, for not having reached a licensing agreement that was expansive enough, it is odd that in this case, where J&J have walked away from the Pool, there has been relative silence. Most commentators agree that the Gilead agreement does not go far enough, and companies and the MPP need to be encouraged to go further, but it is regrettable that Gilead received so much criticism in spite of their contribution to MPP, while J& J, arguing that engaging in bilateral voluntary licensing is sufficient, have not been unilaterally admonished.

Some of the reasons J& J gave for not joining the MPP were at best ill thought out and at worst, misleading. For example, J&J stressed its drugs were available at low cost in

developing countries, and that it preferred to agree bilateral licences with generic companies to ensure adequate quality and monitoring of use (Jack 2011). This suggests that licensing to several companies through the MPP would lead to low quality medicines and resistance, for which there is absolutely no evidence. In the same article, Global Head of J&J, Paul Stoffels, referring to fixed dose combination therapy, suggested 'the mixing and matching of medicines is not a good idea' (Jack 2011). This is at best confusing, because we are sure J&J share universal concerns about producing the most appropriate treatment regimens. However this cannot be achieved whilst withholding access to licences, but only by working with the MPP to ensure the right combinations and treatments are available.

The current access to HIV/AIDS medicines landscape needs a shift of seismic proportions if treatment is to be improved. Amongst other things, the poor state of voluntary licensing practice is a major contributor. It is clear that bilateral voluntary licences are not solving the problem of lack of access and poor affordability of treatments. In addition, licensing negotiations between companies are generally opaque and exclude other stakeholders, which results in licensing conditions that tend to be very restrictive. For example, the geographical scope varies widely and excludes many territories and some of the licences do not allow for robust generic competition that will lower the price.

As yet, there are no generic producers for J&J's darunavir and etravirine, which are recommended third line treatments by WHO and as a result they remain unaffordable in many developing countries (MSF, 2012). At present, darunavir and etravirine licences are limited in geographical scope and focus primarily on registration, packaging and distribution. The US National Institutes of Health (NIH) have licensed darunavir patents to the Pool, but for generic production and sale of darunavir to take place where it is patented, licences are also required from J&J (MSF, 2012).

Opaque bilateral voluntary licences are not a substitute for transparent licensing to the MPP. Companies should not be allowed to get away with making misleading and dismissive arguments when they end negotiations and we hope the companies currently considering or in negotiation with MPP will not choose a similar route as their 'industry best practice' partners.

Let's hope that the Access to Medicines Index 2012 reflects the fact that J&J in turning its back on MPP has potentially also turned its back on millions of people living with HIV/AIDs in developing countries, and condemned them to a future without treatment.

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