HAI EUROPE RESPONSE

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This response has been prepared by Health Action International (HAI) Europe. HAI Europe is a non-profit European network of consumers, public interest NGOs, health care providers, academics, media and individuals with over 25 years experience in representing the voice of civil society, and poor and marginalised people in medicines policy debates.

Our authority rests on our integrity and independence from commercial and political party interests, our research excellence and evidence-based advocacy.

- HAI Europe advocates for access to essential treatments that satisfy the priority health care needs of the population.

- HAI Europe promotes better access to medicines by advocating for EU trade policies that are coherent with the EU's commitments on health and development. HAI Europe campaigns for changes to the EU's internal market laws that hamper access to medicines in Europe and for the exploration of new models of medical innovation.

- HAI Europe supports the rational use of medicines concept, including better controls on medicines promotion and the provision of medicines' information from independent sources, not from commercial entities.

- HAI Europe advocates for the highest levels of transparency, independence and accountability in all aspects of pharmaceutical policy and regulation. HAI Europe calls for greater participation of patients and consumers in adverse drug reactions' reporting and in decisions that will affect their health and wellbeing.

Summary

HAI Europe welcomes the initiative to evaluate the application of the Directive on Intellectual Property (IP) Enforcement. We have, however, identified key shortcomings in the evaluation process and in the content of the Analysis and Report produced by the European Commission.

HAI Europe calls on the European Commission to take into account the wider context of IP enforcement and to consider the social impact of these measures, in particular on health services and access to medicines. An analysis that does not balance citizens' interests and public health needs with property right and IP enforcement fails to fulfill the European Commission's commitment to ensuring *Health in all policies*.

Executive Agency for Health and Consumers

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Lack of coherence with the public health perspective

The concerns presented in the Analysis and the Report were framed in terms of securing right-holders' entitlements to protect and profit from their property. This perspective fails to consider the public health dimension of IP enforcement. To exclude health issues when discussing medicines' patents is worrisome, not least for its lack of consideration for implications on consumer and patient access to medicines, but also for the fact that it disregards the effect on public health expenditure for Member States. This omission highlights the need for a more integrated approach to IP – one that considers the wider social and welfare implications.

The Report came from the European Commission as a whole, yet its content only reflects the perspective of a limited number of Directorates. There was no coherence in DG Internal Market's position on IP enforcement with either DG Competition's established aim to stimulate competition in the pharmaceutical sector to benefit consumers, or DG SANCO's mandate to promote equitable access to healthcare services to patients and consumers across Europe. This narrow approach starkly contrasts with expectations of an integrated and overarching response from the European Commission.

Inappropriate balance between health and property rights

The Commission refers to the Charter Fundamental Rights of the European Union, which contains the right to protection of IP and the right to privacy (Analysis, section 2.4.2; Report, section 3.4). To strike a fair balance between these two rights, it must be acknowledged that the right to privacy is not only a fundamental Community right, but more importantly, a human right established in the European Court of Human Rights, while the right to IP has no such character. As a consumer organisation, HAI Europe considers that the right to generate profit from exclusivity is an unfortunate misappropriation of the human rights discourse.

Excessive emphasis on rights-holder entitlement

The Analysis exaggerates the rights-holder's entitlement to protect their investments by promoting sweeping powers, showing little concern for the impact that this could have on the quality of public health and EU member states' public health expenditure. Specifically, the Commission highlights the use of interlocutory injunctions as an enforcement remedy (Analysis, section 2.5.1.1). The potential for abuse of provisional measures, such as seizures, is high as these measures can be taken even before an infringement is established by a judicial authority. The element of due process is relevant here; as such an establishment requires evidence, hearing the suspected infringing party and properly deliberating the case's merits (Analysis, section 2.3.1). Successful use of the (threat of) interlocutory injunctions to reach a settlement, thereby avoiding the checks and balances laid down in judicial proceedings, is not a sign of effective enforcement, but rather a reflection of a difference in resources and capacity to engage in (costly) proceedings between the rights-holder and the alleged infringer.

In the case of pharmaceutical products, the proposed measures could see legitimate trade in medicines interrupted or suspended on the mere suspicion of an IP infringement (Analysis, section 2.2). Generic companies, by nature of their limited resources, would be less able to challenge frivolous allegations of patent infringements and would be more at risk from the provisional measures. Any injunction against a generic producer would deprive healthcare systems and consumers of affordable medicines. Neither the Analysis nor the Report consider the consequences and costs for citizens of over-reaching 'dissuasive' measures for legitimate competitors (Report, section 3.5). Provisional injunctions should therefore require a high burden

of proof and only be awarded if the right holder can establish that an injunction is the only necessary means to preserve evidence or prevent harm.

Enforcing private monopolies at public cost

The Commission's proposed criminal measures for IP enforcement again over-reach in terms of balance between health and property balance (Analysis 3). Whilst rights-holders are entitled to pursue civil cases on suspected infringements of their private rights at their own cost, criminal proceedings would require public resources. Protecting private rights would become a public responsibility where the burden of enforcement falls on taxpayers. It is inappropriate for the enforcement of private rights to supersede more pertinent public priorities, such as upholding health and ensuring the quality, safety and efficacy of medicines through proper regulation. [i]

Threats to parallel-traded medicines in Europe

Competition from parallel-traded medicines plays a role in medicines affordability in Europe. Not only are parallel-imported medicines cheaper than other medicines not subject to parallel trade, but pharmaceutical companies also accommodate these low-price competitors by reducing their prices over time. These beneficial effects are dependent on active parallel trade. Evidence shows that medicines prices continue to drop as more parallel traders enter the market and sell their products in the same therapeutic class.[ii]

The Commission describes intermediaries as playing a key role in controlling IP infringements (Report, section 3.3). HAI Europe is concerned that the inclusion of "carriers, freight forwarders, shipping agents or postal services" as intermediaries could have a chilling effect on the internal trade in generics and legitimate parallel trade in medicines (Analysis, section 2.5.1.2). Intermediaries have neither the expertise nor the resources to verify an IP infringement. If threatened by an injunction by a rights-holder, an intermediary is likely to minimise risk by terminating further transportation of any goods suspected of infringement – even if the goods concerned are fully legitimate. A chilling effect on parallel trade could have a detrimental impact on medicines prices and availability in Europe.

Imbalanced representation of stakeholders

The Commission's Analysis and Report were produced based on information sought from external stakeholders. As well as 'topping up' incomplete information from the Member States submissions, business representatives were awarded another opportunity to provide input under the 'Stakeholder' submissions (Analysis, annex 2). Not only does this practice neglect the views of civil society, but it threatens the integrity of the methodology used to conduct the analysis by counting one stakeholder group twice. It is imperative to solicit the views of distinct stakeholders in order to conduct a balanced examination of the application of the Directive.

Globalising enforcement rules

In signing the Doha Declaration, the EU has explicitly declared that TRIPS should be implemented and interpreted in a way that supports public health. Despite these commitments, the Commission has gone beyond the minimum provisions in the TRIPS Agreement, namely through Articles 6 and 7 in the Directive, and is attempting to limit the ability of developing countries to use TRIPS safeguards to protect public health. The Report refers to the 'export' of these over-reaching IP enforcement measures to third countries, without regard for the country's development level (Report, section 2). The implementation of these measures will force

developing countries to divert government resources into protecting the patents of pharmaceutical companies largely based in industrial countries, to the detriment of more pressing public priorities, such as health, and universal access to essential medicines. In this way, the EU's IP policies undermine the efforts of other Directorates within the European Commission, as well as the efforts of EU Member States, to promote access to health care in developing countries.[iii]

Strong IP enforcement despite the lack of therapeutically-beneficial medicines

The strong enforcement measures proposed in the Directive, the Analysis and the Report are sustained by the contentious assertion that the IP rights system is an essential means to promote innovation and creativity (Report, sections 1 and 4). This connection has not been substantiated nor has there been an economic analysis of the impact of this Directive on innovation, as the Commission found that experience in applying the Directive is limited. Despite strong IP enforcement rights, there is a lack of truly innovative medicines of added therapeutic value on the market, thus these assertions seem to be unfounded.

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[i] Carsten Fink, Enforcing Intellectual Property Rights: An Economic Perspective, ICTSD, Intellectual Property and Sustainable Development Series, February 2009

[ii] Ganslandt M, Maskus KE. (2004) Parallel imports and the pricing of pharmaceutical products: Evidence from the European Union. Journal of Health Economics 23, pp. 1035-1057.

[iii] Malpani R, Bloemen S. (2009) Trading Away Access to Medicines. Published by Oxfam International and HAI Europe.