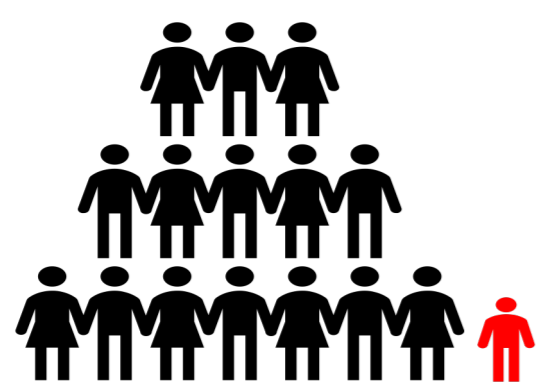




Research Background

- The drug Sofosbuvir (brand name Sovaldi) was launched by Gilead Sciences in 2014 as a novel treatment against Hepatitis C (HCV).
- The drug promised to provide an alternative to previously often ineffective, expensive and traumatic treatments against Hep C as an effective, low-risk treatment that can significantly reduce the long-term consequences of the virus and potentially even cure people infected.
- However, the original pricing strategy employed by Gilead Sciences - \$1000 per pill or a total of \$84,000 per course of treatment - rendered a vast number of patients unable to afford the treatment and access a potentially lifesaving drug.



In 2016, an estimated 71 million people had chronic HCV. WHO estimates that 2.8 million people had been treated with sofosbuvir based treatment regimens by the end of 2016.



In 2015 and 2016 Gilead Sciences reported that sales of its HCV products reached \$19 billion and \$15 billion, respectively.

- As a result of its efficacy, its high prices and limited patient access, Sofosbuvir has been at the centre of a global debate over predatory pricing practices in the pharmaceutical industry.
- The growing literature on 'biofinance' (Glabau, Fioreck and Sherman, 2017) or the 'bio-economy' (Birch, 2017) has highlighted controversies arising from the coupling of moral, social, political and economic values in a single object, such as a medical device or medication (Glabau, 2017; Geiger and Gross, 2019).
- By focusing on Sofosbuvir, this study interrogates the biomedical object as ontologically multiple (Mol, 2002); as a patent, as an asset and as a life-saving drug. It asks how and when these different ontologies are taken into account and being accounted for.



Case Study

- **European Patent Office (EPO) – Sofosbuvir Patent(s) challenges**
- In 2018, 17 activist organisations filed several challenges in opposition to patents relating to Sofosbuvir granted by the EPO.
- These patent challenges confront the patent system, a system that is claimed to enable monopoly pricing practices, but they also raise important questions over the multiple ontologies of a medication.

Research Aims

- By tracing the actors, arguments and vocabularies involved in the EPO application and subsequent patent challenges, we ask how the different actors involved view, interact and come to understand what Sofosbuvir *is* and what effect the patent system has on these understandings and interactions.
- In focusing on one of the structures behind pricing – patenting – instead of the price itself, we seek to provide a different perspective of the Sofosbuvir pricing controversy, highlighting the multiplicities and singularities involved in pharmaceutical pricing

Methodology

- The research is designed with two clear tracks, which run in parallel:
 - an archival (documentary) study of Gilead Sciences EPO patent applications for Sofosbuvir, and the subsequent patent opposition challenges.
 - observations and interviews with the actors involved in the EPO patent challenge and others involved in the medicine patent system.

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