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Guan Yue, 28 August 2024, first published by IAM

In May 2024, China Judgements Online – the official online database of court judgments – published three Supreme People's Court decisions (in which it was acting as a court of appeal) in three parallel proceedings involving pharma giant Sanofi's patents for teriflunomide (brand name Aubagio).

Teriflunomide was initially approved by the US Food and Drug Administration in September 2012 for the treatment of relapsing forms of multiple sclerosis (MS) in adults. In China, MS was recognised as a rare disease in May 2018, and in July that year, Aubagio was approved for marketing. In 2019, Aubagio was included in the national medical insurance catalogue. China's pharmaceutical industry body has released statistics that indicate that Aubagio beat rival MS medications and has long dominated the Chinese market.

The court's rulings

The decisions concern two administrative proceedings and one civil infringement proceeding.

In the administrative proceedings, the court affirmed two decisions (51258 and 51302) made by the China National Intellectual Property Administration (CNIPA) regarding the validity of Sanofi's formulation patents covering the Aubagio tablets, which are both set to expire on 14 September 2030 (ZL201510052300.9 and ZL201510052299.X). The invalidation requests were filed on 15 October 2020 by the same petitioner – a natural person who was likely acting on a generic drug maker's behalf.

The main focus of the disputes was whether the petitioner's technical solution was the closest prior art in assessing the patents' inventiveness.

Sanofi argued that the R&D of a pharmaceutical formulation begins with the active pharmaceutical ingredient (API). Where the teriflunomide compound and a formulation containing another API (compound C) are disclosed simultaneously in the prior art, those skilled in the art would start with the to-be-developed teriflunomide rather than compound C. For the formulation containing teriflunomide as the API, there is no enlightenment in the prior art.

The court disagreed. It opined that achieving better therapeutic effects is at the heart of pharmaceutical R&D. Although the process to develop a suitable formulation is usually based on an API, for drugs that share a common main structure of APIs, it is possible to meet the R&D objective by replacing one API with another based on the existing formulation to achieve better efficacy.

In the meantime, stability remains fundamental in formulation R&D due to its relevance in maintaining drug activity and safety. Individuals skilled in the art would thus note these elements on compound C. Thus, compound C – which is a formulation containing the API with the common main structure of teriflunomide – can be deemed as the closest prior art, and the formulations claimed in the two disputed patents are obvious and non-inventive.

Therefore, on 18 February 2024, the court ruled that the patents should be invalidated. These decisions will wipe out all of Sanofi's Chinese patents related to teriflunomide tablets.

Sanofi initiated a civil suit, seeking affirmation that a Chinese pharma company's generic teriflunomide tablets fell within the scope of protection of patent ZL201510052300.9. The suit was quickly dismissed on 22 February 2024 – days after the court upheld the CNIPA's invalidity decisions.

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The road ahead

The invalidation of Sanofi’s patents will prove to be a boon for Chinese generic drugmakers. Indeed, on 31 December 2021 and 18 June 2024, the National Medical Products Administration – China’s pharma watchdog – granted the marketing applications for generic teriflunomide tablets filed by two Chinese generic drug manufacturers.

Considering the rather low rate of reversal in China’s retrial process, it seems unlikely that Sanofi will be able to revive its patents through retrial, should it opt to initiate one. It is therefore anticipated that the future influx of generic versions of teriflunomide will trigger significant price slashing of Sanofi's teriflunomide tablets in the Chinese market.