AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Tuesday, 11 February 2025

Subject: Raising concerns with the European Parliament's position on the Compulsory Licensing of Patents

To whom this may concern,

As preparations continue for the upcoming trilogue discussions on the European Commission's proposal for a regulation on the compulsory licensing of patents, the American Chamber of Commerce to the European Union (AmCham EU) would like to share critical considerations to ensure that the final regulation supports a competitive and robust EU intellectual property (IP) framework that continues to drive innovation and economic growth.

The progress reflected in the Council's position, particularly its emphasis on the use of compulsory licensing as a last-resort mechanism, maintaining the protection of trade secrets (Articles 2[2], 2[3], 60, 60a, Recital 13), and greater participation rights for rights holders in the licensing process (Recital 3, 21a, Articles 4[d], 6[1, d]) is encouraging. Similarly, the provisions for narrowly tailored licenses (Article 4) and automatic termination of a compulsory license post-crisis (Article 5[1]) are welcomed improvements to the text.

However, further attention is needed on two key points:

1. **Independent judicial review:** Beyond the involvement of the patent holder, independent judicial oversight from a judicial body at all stages of the compulsory licensing process is essential. Such oversight enables rights holders to seek timely and effective judicial review of compulsory licensing decisions. This is crucial to protect IP rights in line with EU law, guaranteeing the rule of law and investor confidence.
2. **Scope of patent applications:** Compulsory licenses should be narrowly tailored to patents directly relevant to the crisis at hand. Broad application of compulsory licenses could discourage investment in critical sectors, particularly during times of crisis.

Regarding the European Parliament's draft, several concerns are outlined below:

1. **Trade secrets (Article 13 [a][2])**: Although the Parliament's position seeks to include certain safeguards on trade secrets, strong concerns remain regarding the potential mandatory disclosure of trade secrets and know-how. Given the inherent nature of trade secrets, mandatory disclosure would irrevocably harm innovators. It would also fail to achieve the stated purpose of enabling the production of complex products such as vaccines. This is due to the complex range of practical factors beyond trade secrets that are a prerequisite for the successful transfer of know how or technology, such as technical capability, sourcing of inputs, workforce training and prior working relationship. This transfer can only be achieved on a voluntary basis. Moreover, such

a transfer would not only violate WTO rules, as the TRIPS Agreement does not allow for trade secrets to be subject to compulsory licenses, but also undermine the EU's wider work, including with G7 allies, to counter forced tech transfer globally.

2. **Remuneration (Articles 9[3]; 13[a][4]):** Terms such as 'adequate remuneration' and 'compensation' do not explicitly give parties the flexibility to agree on terms reflecting the value of trade secrets disclosed.
3. **Protective measures (Article 13[a][3]):** With regard to 'putting in place protective measures (e.g. via confidentiality agreements) to safeguard trade secrets', it is not clear if rights holders can suspend or withhold disclosure if protective measures are deemed insufficient for protecting their trade secrets.
4. **Commission role recital 32(a) in relation to Article 13:** The Commission's ability to determine adequacy of measures and ensure rights-holder consultation needs to be clarified. How will the Commission make this determination, and where does the rights holder's input come into play?

Should you have any questions or wish to discuss our position further, please do not hesitate to contact me directly.

Thank you for your consideration.

Simona Popa,
Chair
Intellectual Property Committee
AmCham EU