US Courts and the European Commission Further Limit “No Challenge” Clauses in License Agreements

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On January 14, 2013, the US Supreme Court denied a certiorari petition by Rates Technology and let stand the decision of the US Court of Appeals for the 2nd Circuit (“Second Circuit”) in Rates Technology v. Speakeasy, 685 F.3d 163 (2d Cir. 2012). The Second Circuit held that a clause in a license agreement barring the licensee from challenging the licensed patent(s) (“no challenge” clause) is unenforceable, even where the license agreement is concluded as part of a settlement entered into prior to the initiation of patent litigation between the parties. The restrictive approach of this decision regarding “no challenge” clauses corresponds to the current approach of European competition law, namely Article 5 Sec. 1(c) of the block exemption regulation for technology transfer agreements (“TT-BER”), which provides that such clauses do not benefit from the “safe harbor” of the TT-BER, i.e. may, based on a case-by-case analysis, be anti-competitive.

Moreover, the Second Circuit in Rates also held invalid a clause in the license agreement which required the licensee to pay damages for challenging the validity of the patent. The decision thus not only limits the use of “no challenge” clauses, but also restricts the possibility of the licensor to dis-incentivize challenges to the licensed patents, e.g., by providing for financial penalties or the right for the licensor to terminate the license agreement (in the following referred to as “sanctions for challenge” clauses). Similarly, the European Commission recently proposed a new, revised TT-BER, which will probably replace the existing TT-BER by May 2014, which will place “sanctions for challenge” clauses under increased competition law scrutiny.
“No challenge” clauses in license agreements – The decision of the Second Circuit in *Rates* reflects the legal development on this issue both in the US and the EU in recent years. Until the 1960s, licensees were not permitted to challenge licensed patents under US law, based on licensee estoppel. In 1969, the Supreme Court dismissed this concept in *Lear v. Adkins*, 395 U.S. 653 (1969), arguing that (i) it was in the public interest to invalidate patents which did not meet patentability requirements in order to protect free competition and (ii) that licensees should have the right to challenge the licensed patent’s validity, because typically licensees were the only parties with sufficient economic incentive to do so. The Supreme Court broadened and clarified the right of the licensee to challenge licensed patents in its landmark decision of 2007.

In the EU, the current TT-BER was enacted in 2004, providing in Article 5 Sec. 1(c) that “no-challenge” clauses cannot benefit from the “safe harbor” of the TT-BER and therefore are not *per se* permitted under EU competition law (even if the other requirements for the application of the TT-BER are fulfilled). They are instead to be assessed individually on a case-by-case basis.

“No challenge” clauses in settlement agreements – However, in *Rates*, the Second Circuit went beyond the supreme court’s 2007 decision by invalidating a “no challenge” clause in a settlement agreement. Such agreements had been considered “safe” from competition policy scrutiny, because it was thought that public interest in settling disputes overrides other possible policy considerations. For example, the Federal Circuit had previously upheld a “no-challenge” clause in a settlement agreement in *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d at 1370 (2001). The Second Circuit distinguished this case by arguing that in *Flex-Foot*, the accused infringer had had an opportunity to conduct discovery on validity, whereas in *Rates*, there had been no discovery. This was significant for two reasons: “First, it suggests that the alleged infringer has had a full opportunity to assess the validity of the patent, and is therefore making an informed decision to abandon her challenge to its validity. Second, the fact that parties have conducted discovery is evidence that they had a genuine dispute over the patent’s validity, and that the patent owner is not seeking to block challenges to its monopoly by characterizing ordinary licensing agreements as settlement agreements.”

Under EU competition law, “no challenge” clauses in settlement agreements are – currently – generally considered not to infringe EU competition law. This is because, according to the EU Commission, it is “inherent in such agreements that the parties agree not to challenge ex post the intellectual property rights covered by the agreement. Indeed, the very purpose of the agreement is to settle existing disputes and/or to avoid future disputes.” However, according to the draft guidelines for the new TT-BER, the EU Commission has made, based on its decisions in *AstraZeneca* and *Lundbeck*, two important caveats for when a licensee should still be entitled to challenge licensed patents: First, if the licensor “knows or could reasonably be expected to know” that the licensed patents could be invalid, and second, if the licensor induces, financially or otherwise, the licensee to agree not to challenge the validity of the IP right. Thus, currently, there is an increased risk that companies may have to revise their settlement agreements to bring them into conformity with the revised rules, if those rules will be adopted by the EU Commission and take effect next May.

Financial sanctions to dis-incentivize challenges to patent validity – As a result of the restrictive approach both in the US and the EU with regard to “no challenge” clauses, licensors developed other mechanisms to discourage licensees from challenging the licensed patents. In the US, one frequently-used option is to impose financial sanctions on the licensee, e.g., the payment of damages or the payment of increased royalties if the challenge is unsuccessful.
However, the Second Circuit in *Rates* found invalid a clause requiring the licensee to pay damages if it challenged the validity of the patent. The Second Circuit argued that there is no public policy justification for any disincentive to challenges to patent validity by way of “sanctions for challenge” clauses, for very much the same reasons as for “no challenge” clauses.

**The right for the licensor to terminate the license agreement** – In Europe, the typical sanction against the licensee in case of a challenge to licensed patents in license agreements in the pharmaceutical sector is to provide for a right for the licensor to terminate the agreement. If the other requirements for the application of the TT-BER are fulfilled, these termination clauses explicitly fall under Article 5 Sec. 1(c) TT-BER and thus do not infringe EU competition law. However, in the draft TT-BER, which is to replace the current TT-BER in May 2014, the European Commission proposes to provide that termination clauses no longer fall under the TT-BER. Rather, they should be subject to an assessment of possible anti-competitiveness on a case-by-case basis. The European Commission argued that “sanctions for challenge” clauses in practice create a disincentive to invalidate questionable patents similar to “no challenge” clauses. Rather, the licensee should be allowed to challenge a patent’s validity without worrying that the license agreement will be terminated.

**Consequences for drafting license agreements** – Many licensors in the pharmaceutical and healthcare industry have tended to rely on “sanctions for challenge” clauses in license agreements to protect their patents. In particular, these sanctions include financial sanctions and the right of the licensor to terminate the license agreement, as a substitute for “no challenge” clauses, which might otherwise be considered invalid under US case law and anti-competitive in the EU under the current TT-BER. However, in light of the *Rates* decision of the Second Circuit and the proposed new TT-BER, the viability of such “sanctions for challenge” clauses has also become questionable. This puts at risk the validity of licensed patents, the accompanying royalty payments and the underlying capacity to recover research and development costs.

Licensors need to be aware of the increased legal risk when entering into license agreements.

**Recommendations and Considerations** – However, using such clauses may still have some value. In the US, while the Supreme Court has not reversed the decision of the Second Circuit, other Courts of Appeal have not (yet) followed the *Rates* ruling. Under European competition law, even without the protection of the TT-BER, the respective clause could still be exempted from the prohibition of anti-competitive agreements under Article 101(3) of the Treaty on the Functioning of the European Union (TFEU) on a case-by-case basis. The resulting legal insecurity may continue to work as a disincentive to challenges to patent validity by the licensee.

Licensors should also consider other options to protect their licensed patents and, by extension, royalty payments. For example, it may be helpful to add language in the representations and warranties section that the licensee has had an opportunity to assess the validity of the licensed patent. Also, if the licensor grants a patent license, but also provides accompanying know-how, the license agreement should expressly specify that royalties are payable partly for the license of the patent technology and partly for the use of the know-how. In this way, a share of the royalties will be payable even if the patent is invalidated (or expires).