

## Life Sciences Should Brace For Fla. Rad Source Ruling

*Law360, New York (March 26, 2014, 10:55 PM ET)* -- Some of the most innovative new products arising out of the life sciences industry have passed through multiple hands before reaching physicians, caregivers and patients. Insights and early discoveries in academic laboratories are often validated, translated and tested by small companies and, upon proof-of-concept, those products are then frequently licensed to large, global companies for commercialization. Not surprisingly, intellectual property rights covering those products are conveyed throughout the discovery and development value chain through license arrangements.

Generally speaking, exclusive licenses to intellectual property rights covering life sciences products carry the right to grant sublicenses in order to facilitate the downstream development and commercialization of those products. While restrictions or bounds on sublicense grants are sometimes negotiated, it is a rare instance when the licensor retains the right to approve a sublicense in advance. Instead, the rights of the licensor are protected by a requirement in most sublicense clauses that the licensee/sublicensor remains obligated to the original licensor under the terms of the license agreement, even with respect to the activities of a sublicensee.

Another provision commonly negotiated in license agreements is the right to assign the agreement to a third party in its entirety. These provisions, once negotiated, fall across a broad spectrum — from a prohibition on assignment in all instances, to a prohibition on assignment without the other party's consent, a prohibition on assignment without consent except in specific circumstances (e.g., to affiliates and/or in connection with a merger, business combination or the sale of all or substantially all of the assets of a party to which the agreement relates) to the unfettered right to assign, either with or without notice to the other party.

The distinction between an exclusive sublicense and an assignment is almost intuitive for licensing practitioners. However, a case currently being considered by the Supreme Court of Florida may establish concrete distinctions between exclusive licenses and assignments, and the court's decision may have a significant impact on how these provisions are drafted and negotiated in the future.

### The Rad Source Case

This case, *MDS (Canada) Inc. et als. v. Rad Source Technologies Inc.*, is centered around a contract dispute between Rad Source Technologies and MDS Nordion. Rad Source developed a blood irradiation device called the RS 3000 that used X-rays, rather than radioactive isotopes, to reduce the risk of Graft-versus-host disease following blood transfusions.

In 2002, Nordion, a health sciences company with resources capable of bringing RS 3000 into the

international market, contacted Rad Source to license its technology. After lengthy negotiations, the two parties agreed to a license agreement, governed by Florida law, the terms of which required Rad Source's consent if Nordion were to assign its rights under the contract, but which also gave Nordion the unfettered right to grant sublicenses under the intellectual property rights granted by Rad Source.

In 2007, Nordion decided to exit the blood irradiation market and entered into negotiations with Best Medical to sell its assets. Nordion asked for Rad Source's consent to assign its rights under the licensing agreement to Best. Rad Source refused on the grounds that Best was its competitor, a decision that the Eleventh Circuit would later uphold as reasonable. As a result, Nordion and Best instead entered into a sublicense agreement without Rad Source's consent, whereby Nordion decided to grant Best all of its rights under the license agreement, for a term equal to the term of the license agreement with Rad Source, minus one day.

Amidst a bevy of claims and counterclaims, Rad Source asserted that Nordion's sublicense with Best was, given its duration, an assignment by any other name. Accordingly, Rad Source argued that Nordion breached the license agreement for failing to obtain its consent.

The U.S. District Court for the Southern District of Florida agreed with Rad Source, and this decision was appealed by Nordion to the Eleventh Circuit. As to the specific question of whether the sublicense to Best was an assignment in breach of contract, such a breach being a question of Florida law, the Eleventh Circuit was divided.

The majority effectively couldn't decide how to answer the question and instead asked the Florida Supreme Court to do so by asking the following certified question: "When a licensee enters into a contract to transfer all of its interests in a license agreement for an entire term of a license agreement, save one day, but remains liable to the licensor under the license agreement, is the contract an assignment of the license agreement, or is the contract a sublicense?"

In dissent, Circuit Judge William Pryor contended that Florida law is unambiguous; the agreement between Nordion and Best is a sublicense. Judge Pryor analogized to a long line of Florida cases involving real estate subleases on the theory that leases, like licenses, are a right to use someone else's property — a leap a majority on the Eleventh Circuit was unwilling to take — arguing that there is a "bright-line" rule distinguishing subleases from assignments with the key criterion being whether "the entire interest in the term is transferred without a reversion being retained by the original lessee."

Translating that to the license context, Judge Pryor also argued that, if a sublicensor is not liable on the original contract and retains no rights to enforce it, then it is an assignment. Similarly, if a sublicensee has no recourse against the original licensor, and only against the sublicensor, then the agreement is, indeed, a sublicense.

### **What's at Stake?**

Last month, oral argument in this case was heard before the Florida Supreme Court, and the life sciences industry is awaiting the court's decision with interest. If the state's high court were to depart from the bright line rule in this case it would represent the classic situation of "bad facts making bad law."

The facts clearly demonstrate Nordion's intent to circumvent the anti-assignment provision of its agreement with Rad Source. It entered into an asset purchase agreement with Best for the business to which the RS 3000 device related. When Rad Source objected — reasonably so according to the courts

hearing this case — to the assignment, Nordion looked to the sublicense provision in the agreement as a “work-around” to convey exclusive rights to the asset to Best.

Moreover, the one-day difference in term appeared to have no commercial substance other than to fall on the side of the “bright line” to characterize the relationship as a sublicense. During oral argument, a number of Justices expressed skepticism over the characterization of the arrangement as a sublicense in light of the facts and questioned whether Rad Source truly had any recourse against Nordion under the sublicense in light of the associated asset sale to Best.

At the same time, the Justices appeared to grapple with identifying the factors, if any, that would be dispositive in determining whether a conveyance of rights is a sublicense or an assignment. To be sure, these factors could vary from transaction to transaction based on the relevant markets and technologies. Given the fact-intensive nature of the myriad licensing transactions entered in the life sciences industry, departure from the bright-line test could create substantial uncertainty for parties entering sublicense agreements and potentially lead to future litigation.

For example, if a one-day difference in term is too short, is one month sufficient? Or, if a sublicensor were to reserve rights to market a product to red-headed, left-handed girls under age 18 in Massachusetts, with all other rights being conveyed to a third party, could that be construed as an assignment instead of a sublicense? Moreover, a decision permitting subjective assessments of whether adequate recourse is available under a contract in order to assess whether it is a sublicense or assignment would create even greater uncertainty.

A decision is expected soon, and it is entirely possible the Florida Supreme Court will answer the certified question narrowly, on the facts of this case. It is also possible the court may replace the bright line rule with a set of general principles around which future courts would assess whether the grant of a sublicense under all of a licensee’s rights under license agreement is an assignment in another form.

If the latter, it is then possible that this decision could have persuasive authority in a number of states that have adopted the bright-line test and which commonly govern license agreements in the life sciences industry, including New York and Massachusetts. If this comes to pass, the Florida court’s decision in *MDS v Rad Source* could necessitate changes in licensing practice.

### **Practical Advice Moving Forward**

In the meantime, counsel representing exclusive licensees should consider the following practice points:

- Negotiate the anti-assignment clause so that the licensor does not have a consent right over a corporate transaction that would result in an assignment of the license agreement, such as asset sales of the nature negotiated by Nordion and Best, including assignments as a matter of law such as in a merger. Licensors are entitled to notice of these assignments, and it is often reasonable to ask the assignee to acknowledge in writing that it will agree to adhere to its obligations under the agreement; but, giving a licensor the right to determine the fate of a strategic transaction by its exclusive licensee can lead to unanticipated results.
- Include a statement in the assignment clause to the effect of, “[T]he sublicense of all or substantially all of the rights granted hereunder to a third party will not be considered an assignment of this agreement, provided that [licensee] remains obligated to [licensor] for compliance with all applicable terms and conditions of this agreement.”

- When negotiating sublicenses that are intended to be exclusive, explore opportunities for the sublicensor to retain a substantial interest in the intellectual property right, whether for research purposes, in a particular field, or in a specified territory, to avoid any implication that the sublicense is an assignment.

The level of interconnectedness among players in the life sciences industry is one of its strengths and clarity around how an exclusive licensee is able to convey its interest in licensed property to a partner is important to promote collaboration and to ensure all industry participants are engaged in their highest and best use. The MDS v. Rad Source case has the potential to change the rules on the field, so everyone should be watching this important case.

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