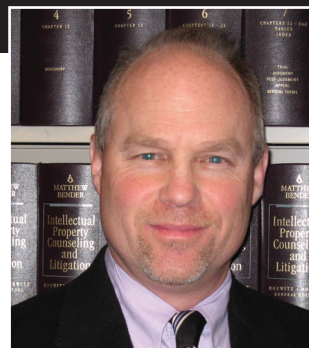


The IP License Agreement: A View from 5,000 Feet



John W. Boger, Esq.
Heslin Rothenberg Farley & Mesiti P.C.

It is commonplace for medical device manufacturers to “license” technology to allow them to either manufacture, sell or develop a product. Licensing of patents, trademarks, copyrights or trade secrets (collectively, intellectual property or IP) from third parties is governed by a special kind of contract called a license agreement that is unique to each licensing relationship. This article will generally discuss many of the critical provisions that should be included in such an agreement.

According to the Merriam-Webster Online Dictionary, the definition of a license is “*permission to act*” or “*freedom to act*.” Typically, a license will be granted by one party (the licensor) to a second party (the licensee) to allow the second party to use the licensed IP for a period of time period to do certain things with that IP.

To create a long and mutually-beneficial relationship, a successfully-crafted license agreement will clearly define what is covered by the license, the length of license terms and amounts to be paid.

Team Formation

Before pen is put to paper on the license agreement, each party must determine their corporate objectives for the license. The fundamental question is, why are you trying to obtain the license, or if you are on the other side, why are you granting the license? Do you need the technology to produce a product, or do you need to raise cash? With these answered, you are then in a position to move to the next step, which is to form the in-house team that will be tasked with negotiating the agreement. The team may include a technology expert, a business development executive, a C-level or equivalent executive who has the decision making authority and an attorney who is familiar with licensing agreements. The team should meet before starting any negotiations to assess the strength of their company’s license position, which may include looking at the company’s current research and development abilities related to the target technology, the competency of the marketing and sales department and a review of the other side’s strength and weaknesses.

Having a handle on your adversary’s abilities will determine the degree of flexibility that you may need to show with any proposed license provisions.

Term Sheets

When two parties decide to move forward with a license “deal,” the first step is to find out what each party wants before drafting and negotiating the actual license agreement. How is this accomplished? Usually, the two parties will try to draw up a Term Sheet. This will list key terms and conditions to be included in the license, and provides a framework for attorneys to draft corresponding clauses for inclusion in the license agreement. Examples of Term Sheet items include the IP definition, term of the agreement, license category (i.e., exclusive, non-exclusive, etc.), royalty rate, royalty rate calculation and payment terms, minimum royalties, indemnification, warranties and termination conditions. Term Sheets are signed by the parties and are usually binding.

The License Agreement Itself

The license agreement spells out the responsibilities of the licensor and licensee for the life of the licensing relationship. However, as my Law School Contracts professor reminded us almost every day in class, when a lawyer is drafting an agreement, he must remember that usually at some point down the road, one of the parties will want a “divorce” and you need to do everything possible in the agreement to protect your client’s interests when this divorce inevitably happens. This advice is very important for licensing agreements because such arrangements usually last for years, and circumstances will inevitably change over this time.

License agreements comprise a series of provisions that address the specific licensing relationship and objectives of the parties. One must be careful to not fall into the “template” agreement trap, because not crafting the provisions to meet the uniqueness of the license relationship may cost one party significantly over the term of the agreement or when the “divorce” occurs.

The first part of the license agreement is an introductory paragraph that states when the contract is effective and gives names and addresses for the parties involved. Subsequent to the introductory paragraph will be the “Whereas” clauses or

recitals. These paragraphs are usually not binding to either party, but rather provide background information on the license grant and reasons why the parties are entering into the relationship. The content of these paragraphs may prove helpful to refresh the memories of the parties, or assist a court in interpreting the intent of the agreement.

The main body of the license agreement is made up of a series of promises that the parties are making to each other. To help interpret these promises, the first paragraph of the body is usually a listing of definitions, included to help the reader understand the full meaning of the subsequent provisions. Examples of defined terms include net sales, patented technology, improvements, affiliate and launch date.

The next series of paragraphs may be classified as the grant provisions. These paragraphs describe in detail the metes and bounds of the license. The first paragraph may describe the license rights granted. This provision will indicate if the license is an exclusive or non-exclusive arrangement for the IP rights, define the IP being licensed and indicate whether know-how is included. The revocability of the license may also be included. A second paragraph may describe what license restrictions exist. Such limitations could include field of use, geographic territory, subject to prior licensee rights, any restrictions on the ability to make, use, export, import or sales of products using the IP rights, etc. The third paragraph may state what license rights are being reserved by the licensor; for example, when a University is involved, they will reserve the right to continue to use the licensed technology for research or educational purposes. The fourth paragraph may delineate the rights to be able to grant sublicenses and any limitations on those sublicense grants. Two additional grant provisions that must be included in the agreement are the specific geographic territories (e.g., worldwide vs. U.S. only) and how long (i.e., term) the license will last. Most agreements have a definitive effective date and an end-date; however, the length of the agreement term may be set by the life of the IP rights, the annual amount of royalty amounts paid to the licensor or the occurrence of a defined, future event.

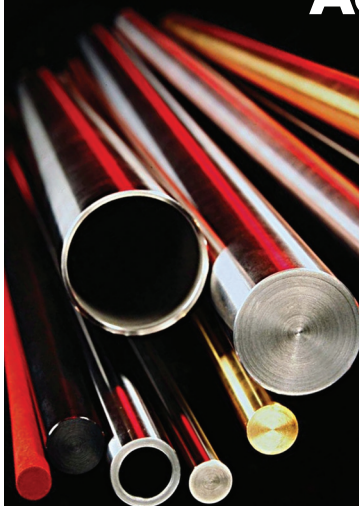
The next provision of the agreement will address what amount of consideration is being paid for the license. Pay-

ment to the licensor will vary depending upon the licensee's financial standing and the technology development timeline. Examples of payment arrangements to the licensor may include a streaming royalty based on a percentage of net or gross sales, specific development or regulatory approval milestone payments in combination with royalty payments, an upfront one-time license fee payment with subsequent streaming roy-

Lower Your Cost

Machine your parts from the best bar in the business.

AccuRod®



- BioDur® 316S stainless
- BioDur® 108 alloy
- BioDur® TrimRite® stainless
- Custom 455® stainless
- Custom 465® stainless
- Titanium alloys
- Tolerances to .000040"
- Finishes to 2Ra



Straightness, roundness and size tolerance are essential to medical component manufacturing. At Boston Centerless, we understand your needs and provide materials precisely to specification each and every time, allowing your machining process to run smoothly. Contact us today for a quote on the best precision bar for your business!

ISO 9001/AS9100 Certified

BioDur, Custom 465, Custom 455 and TrimRite are registered trademarks of CRS Holdings, Inc., a subsidiary of Carpenter Technology Corporation.



Boston Centerless
Precise in everything we do.

11 Presidential Way, Woburn, MA 01801
Phone: 781.994.5000 • Fax: 781.994.5001
info@bostoncenterless.com

800.343.4111

www.bostoncenterless.com

alty payments, or in a very rare case, a single license fee. The types of currency accepted and the royalty payment terms should also be included in this provision.

A separate aspect of the consideration being paid for the license is the inclusion of an “anti-shelving” provision which usually takes the form of a minimum royalty payment requirement. Including such a provision protects the licensor from having their technology “shelved” or not commercialized. This requires the licensee to pay the licensor a threshold amount (usually based on an annual amount). If the streaming royalty payments made by the licensee do not meet or exceed the threshold amount, then the licensee must pay the difference or risk certain consequences, such as having the license agreement terminated, the license rights changed from exclusive to non-exclusive or having some of the licensed IP rights “clawed” back by the licensor.

A subsequent agreement provision should describe what financial reports must be provided by the licensee to the licen-

sor. Generally, these reports will verify and detail to the licensor the basis for the streaming royalty payment calculation. Most reports are provided to the licensor on a quarterly basis with the licensor having the right to perform an audit of the licensee’s records upon notice. Penalties for inaccurate royalty payments by the licensee should be included, as well as a set time limit for record retention.

A key provision for license agreements involving patents is how to address improvements that may be made to the licensed invention or patent during the term of the agreement. Such improvements could be made by either the licensor or the licensee. This provision must explain the obligations for the party that has developed the improvement and whether the improvement is merged into the current agreement or is deemed to fall to the licensor under the reservation of rights paragraph.

Other than the amount of consideration being paid for the license, the provision listing the representations and warranties being made by each of the parties is always the most hotly negotiated. If a party fails to satisfy one of their “reps” or “warrants,” then they will typically have to indemnify the other party for any damages that have been caused by the failure. This section should be broken down into two parts: one for the licensor and one for the licensee. The listing of possible reps and warranties can be very extensive, but the key items typically include that both parties have the authority to enter the license agreement and that both parties will comply with all pertinent laws. As for the licensor, one critical rep is that it has full rights and title for the IP rights being licensed and has no knowledge that the IP being licensed infringes upon any third party’s rights. Additionally, it is advisable for the licensee to get the licensor to warrant that they will maintain the standing of the IP and pay all necessary fees.

The section that describes the obligations of the licensor and licensee in case of infringement of the IP is usually broken down into three parts. The first will detail the responsibility of each of the two parties for enforcing the licensed IP. In most cases, this duty will rest with the licensee. The second part may describe the obligations of the parties if the licensed IP infringes a third party’s rights. The third part may then describe how any recovery of damages for infringement is divided between the parties and any indemnification obligation on the part of the licensor to the licensee, if the licensee is sued for using the licensed IP.

Due to the complexity of the technology, some license agreements will define the licensed IP using a separate provision rather than being covered under the above definitions section. Typically, this only occurs if the license covers an extensive listing of patents, applications, know-how and trade secrets that must be more completely described. Along this same line, a separate provision may also be included to define and address how “Confidential Information” is to be treated. Specific carve-outs must be included for information that is not to be treated as confidential and for information that may be developed or disclosed during the term of the agreement. If preexisting non-disclosure agreements or confidentiality agreements are in place between the parties, these should be suspended by the terms of the license agreement.

Tecomet Acquires Teleflex Medical OEM Orthopaedics Business

Teleflex entered into a definitive agreement to sell its OEM orthopaedics business to Tecomet for \$45.2MM in cash (estimated sales multiple 1.26*). Product lines to be divested include Beere Medical’s custom surgical instruments and SMD micro-machined products (plates, screws, rods, etc.).

Teleflex OEM products, which are marketed under the Beere Medical, KMedic, SMD, Deknatel and TFX OEM brand names, encompass custom-configured extrusion, introducer systems, specialty sutures, resins, yarns, surgical instruments for orthopaedic and spinal procedures and micro-machined fixation devices and components.

Tecomet is a contract manufacturing, engineering and metal fabrication technology company based in Wilmington, Massachusetts. The company specializes in net shape forging, precision machining, photochemical etching, surface texturing, vacuum brazing, laser and electron beam welding and rapid prototyping. Tecomet has a special emphasis on orthopaedic, trauma and spinal implants.

The transaction is expected to close in 3Q12. In 2011, Teleflex Medical OEM’s orthopaedic business generated revenue of ~\$36MM.

REFERENCES

Teleflex Signs Definitive Agreement to Sell OEM Orthopaedics Business for \$45.2 Million. July 18, 2012.

Company press releases, web sites, filings with the Security and Exchange Commission

*ORTHOWORLD estimate

Two more key provisions include the termination and assignment paragraphs. The assignment provision will state that the licensee is not allowed to assign the license to anyone unless prior approval is received. The licensee will try to avoid this required step, as they will want to treat the license agreement as a saleable asset. The termination provision can be either very complicated or quite simple. The purpose of this paragraph is to lay out how either party may end the relationship. Some agreements allow only the parties to end the agreement for material breach. If material breach is the basis for termination, then usually the breaching party will be given an opportunity to cure the breach. Some agreements only terminate when the licensed IP expires, which may be problematic if the licensee is not performing. Generally, termination provisions are hybrids, in that the licensor can terminate for uncured material breach, while the licensee can terminate for uncured material breach or for no reason upon 30 days written notice. Many agreements include the ability of a party to terminate if the other party is deemed insolvent or files for bankruptcy protection, but beware when you see this, because in most cases the Bankruptcy Courts will take over and such termination action will likely be prohibited.

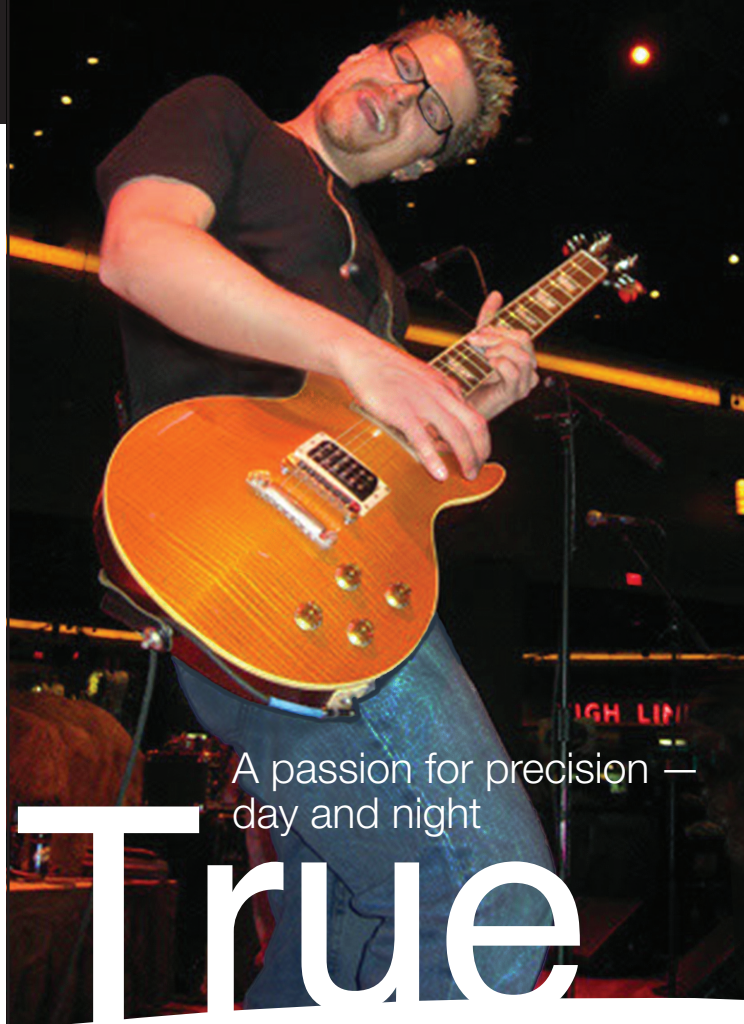
The balance of the provisions in a license agreement is not any less important; however, most will fall under the description of "boilerplate" language. These will address patent marking responsibilities, disclaimer of agency/Independent Contractor status, post-termination clause survival, waivers and modifications to the agreement, notice requirements, compliance with the law, venue and choice of law, entire agreement definition and force majeure requirements.

In conclusion, one must remember that although license agreements may look very similar, they are not created equal. Great care must be taken by both the licensee and licensor to craft a workable document that accurately reflects the licensing relationship between them and clearly defines what is covered by the license, how long the license will last and what amounts must be paid. If these goals are met, then the licensee and licensor may enjoy a long and mutually-beneficial relationship.

This article has been written for informational purposes only and should not be interpreted as legal advice.

John W. Boger is a partner with the Upstate New York law firm of Heslin Rothenberg Farley & Mesiti P.C. and is the Chairman of the firm's Medical Products and Technology Practice Group. Before attending law school, Mr. Boger worked for eight years with a large orthopaedic device manufacturer in various product development and marketing positions. He can be reached at 518-452-5600 or at jwb@hrfmlaw.com.

Heslin Rothenberg Farley & Mesiti P.C.
www.hrfmlaw.com



A passion for precision —
 day and night

True



At **Tegra Medical** our passion for precision shows, day and night. Take our very own Dean Petrella. This laser expert and program manager is passionate

about helping customers manufacture medical devices that improve patient care. Careful listening to customers' needs, precise engineering and manufacturing, and hitting promised delivery dates are all part of his day. At night, you'll find Dean performing with his band The Complaints, where his precise mastery of composing and performing are infused with his passion for rock'n'roll. Yeah, kinda like his day job. **True passion about the work we do.**

That's Tegra Medical.

Learn more about Tegra Medical and check out The Complaints' music and schedule at www.tegramedical.com/dayandnight.



BOSTON

MEMPHIS

COSTA RICA

Copyright © 2012 Tegra Medical. All rights reserved.