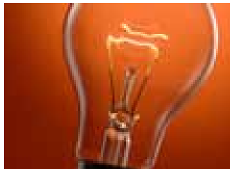

Six Key Ways to Protect Mobile Medical App IP

Anuj Desai and Andrew B. Flake

As a long-term means of protecting value for a mobile medical application (MMA) product, securing core intellectual property tops the list. The technology behind your app may represent most of your company's value, as any number of recent acquisitions of and substantial investments in MMA companies attest. If not deterred, competitors or aspiring competitors can be quick to reverse engineer or otherwise seek to replicate the features of your software, especially if you are an early innovator or disruptor in the market. Yet, especially given how fast-paced and fluid the development environment can be, company management too often gives insufficient attention to the topic of intellectual property protection. Here are six proven ways to implement a robust and well-thought out intellectual property strategy for your MMA:

1. **Seek patent protection early.** To prevent the emergence of a knock off MMA, referencing your pending patent application is powerful medicine. Unfortunately, some of the conventional wisdom being shared suggests wrongly that MMAs are never patent eligible. Yes, some recent case law cuts back on patents in certain areas, for example, business methods, and one cannot patent software in its intangible form. But an MMA is typically not just intangible — it is software turning a mobile device into a medical device —an app connects to a server and runs certain operations, for example, collecting and executing queries or algorithmic functions on data, returning results to the user via a graphical interface on the mobile device. To the extent the software interacts with the mobile device, computer or other equipment, then, patent protection can subsist in various aspects of MMAs. It is also important to look at your MMA holistically in terms of how and where it functions, because you may have the ability to assert related and complementary patent claims on the same application. For example, where the MMA operates on both client and server, there may well be separate potential "systems, devices, and methods" claims at both levels. Importantly, because of a recent change from a "first to invent" to a "first to file" system, it is critical to evaluate potential patent filings immediately. That means getting at least a provisional patent on file as soon as possible, and certainly as soon as possible to avoid the one year on-sale bar. If you have any doubts about what may or may not be patented, you should work with your legal counsel to commission a patent search and further analysis.

2. **Revisit additional patent potential often.** As development continues and new functionality of your MMA is readied for release, periodically query whether an existing patent or application you have on file covers all critical aspects of the updated MMA. Perhaps you are preparing to roll out a new version or upgrade with substantial new features. If so, and considering the cost benefit, a new provisional application may be in order. This ongoing assessment is especially important in health IT development, where companies employ an agile development model. The older waterfall development model —more linear and structured, with design, followed by coding, and then testing and debugging, and release — does not reflect how most health IT companies now work. Code gets revised and deleted right way, with lots of incremental changes. The result is that your MMA may be ready to use before it takes on its final form, making a provisional patent application the right interim step.

3. **Secure your ability to claim trade secret protection.** Smart health IT management will complement other IP techniques with the ability to claim the broadest possible trade secret protection. Obtaining a patent on a system or method is not always the complete or sufficient solution. Among other things, apart from not being available for certain proprietary aspects of your MMA, patent protection is time-limited and requires eventual public disclosure of the invention. But trade secrets are, in essence, any information in most forms that is secret and that creates competitive value for your organization. One of the beauties of trade secret protection is the flexible definition of a trade secret and the fact that, unlike patent or copyright, there is no disclosure requirement. The key here is being able to demonstrate reasonable steps to maintain secrecy — among other things, appropriate agreements with employees and development partners, training and policy documentation related to IP, and virtual and physical security, all appropriate to your particular environment. You'll also want to have a coordinated action plan in place with legal counsel to address the scenario in which any key product development employees leave, especially if they move to a competitor. Speed is of the essence in responding to trade secret theft and minimizing leakage of proprietary information before your competitive advantage is neutralized.

4. **Consider copyright to protect your code.** Another complementary tool is copyright protection for the software code itself. A copyright registration represents another possible arrow in your quiver. Just like the written expression of prose or music is protectable, so, too, generally is original source code. And in the event of true literal copying of that code, a potential copyright claim allows access to federal court jurisdiction and unlocks substantial damages — a strong negotiating lever to pull. Although prior to taking any legal action to enforce the copyright, the company needs to register the copyright. Getting a registration is a fairly straightforward process, and a well-prepared company will periodically obtain registrations for iterations to the source code as new releases of the software are completed. In a pinch, however, registration can also be expedited at the time of the infringement, but doing so after infringement has already occurred prevents you from obtaining the full scope of statutory damages and remedies available. Remember that copyright subsists at the time of creation, which means that once your development team authors the code, the copyright exists. And remember, where you have added contract developers or employees to the product team, you should make sure the new personnel sign an invention and copyright assignment provision documenting and confirming that the technology and underlying source code is yours, not the employees.

5. **Adapt your licensing agreements to the business.** Depending on your business philosophy, there are multiple license strategies your health IT company can employ. The important thing is that, where your company has established a strategy, you should have the legal foundation to support it. A license agreement with your customers, for example, should reflect the specific reality of how your application works and what you consider proprietary: Your customers should understand through clear written delineation what they can and can't do, and an "off the shelf" license agreement pulled from the web or another software product will rarely capture the details that are important to your business. Remember, too, that a good license strategy is offensive and defensive — what technologies might you need, not just to enhance your own product, but to fend off potential competitive claims. Similarly, have you guarded against an unwanted claim of ownership or co-ownership? A raft of disputes arise where someone the software developer thought was just a contractor then later claims an ownership interest in the MMA. And you want to make sure that restrictions on your own company do not impede growth. Are you using open source technology? If so, have you looked to the license terms to see how they work and might apply and what restrictions exist? Are you providing indemnities downstream that you are not in a position to honor? These and similar questions should be answered in drafting a license agreement that is a good fit for your MMA.

6. **Plan for the future.** Your IP protection program should not be reactive; it should be tailored to your growth curve as you see it. In the case of patents, you may want to claim protection for features that can or will be added even if they are not in the current release. How will upgrades in technology and processing power affect the kinds of queries your app runs on data, what functionalities are offered to users, and how the user interface works? What does your customer base look like now and what will it look like in the future? Determine how you want to interact with other HIT vendors and the user community and design accordingly. Are you developing an open or closed platform? Do you want to set forth a standard that others will follow, and, if so, can you still keep that standard proprietary and protect it from unauthorized use? And, in every case, look at your actual and projected revenue stream and ask how your agreements protect it.

Given current trends in the healthcare IT market, including regulatory and clinical pressures to do better faster with health technology, the growth prospects for an innovative MMA are tremendous. Today's startup can truly be tomorrow's market leader. And by thinking through your IP protection strategy in advance, healthcare IT management can put their companies in a position to best capitalize on that opportunity when it arrives.

Authors and Contributors

Anuj Desai
Partner, Atlanta Office
404.873.8658
anuj.desai@agg.com

Andrew B. Flake
Partner, Atlanta Office
404.873.7026
andrew.flake@agg.com

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Atlanta Office
171 17th Street, NW
Suite 2100
Atlanta, GA 30363

Washington, DC Office
1775 Pennsylvania Avenue, NW
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