2018 promises to be rocky time in IP world

Global IP

By Doris Estelle Long

Doris Estelle Long is the president of Doris Long Consulting, specializing in U.S. and international IPR and information security issues; a screenwriter and producer for VeraKen Productions; and a law professor emeritus at The John Marshall Law School. She has served as a consultant on IPR issues for diverse U.S. and foreign government agencies, including as attorney adviser in the Office of Legislative and International Affairs of the USPTO. She can be reached at prof.doris.long@gmail.com.

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If you don't have any international protection issues on your 2018 to-do list, you aren't alone. This past year has seen tremendous upheavals in domestic intellectual property law.

From the elimination of disparaging (and most likely scandalous) mark registration refusals (*Tam*) to the rewrite of the rules governing copyright eligibility for the design features of useful articles (*Star Athletica*), the establishment of international patent exhaustion (*Impression Products*) and the creation of a new standard for design patent damages (*Samsung*), the Supreme Court has rewritten critical aspects of intellectual property law across all fields.

It is poised to rewrite the rules for the Patent Trial and Appeal Board (*Oil States*). These developments, along with continuing issues regarding the limitations of *Alice* and *Prometheus* on patentability and the emerging issues surrounding artificial intelligence–based innovations and works are enough to fill anyone's 2018 to-do list.

But just as withdrawal from the Trans-Pacific Partnership did not stop the remaining countries from crafting a free-trade zone without the United States, international issues are continuing to develop without U.S. participation.

The current arc does not bode well for U.S. IP owners. In short, 2018 could well become the Year of Diminishing IP Rights. Sitting on the sidelines is the last thing U.S. IP owners need to do. Instead, proactivity should become next year's watchword.

In brief, among the critical issues IP owners will face are the following:

For patent holders

1. Conflicts over reasonably priced access to patented pharmaceuticals will grow hotter and more diverse.
2. Delinking patent ownership and market approvals subject to future WIPO action.

For trademark and design holders

1. Continuing stumbling blocks to post-Brexit protections remain and may grow.

For copyright holders

1. Movement to carve out expanded fair-use treaty-based exceptions and limitations is gaining momentum.
2. Conflicts over application of Marrakesh Treaty exceptions for the visually impaired will increase and fuel additional global piracy.

For all IP owners

1. Global piracy will increase as international enforcement infrastructure continues to crumble in face of U.S. retreat.
2. International "enforcement" replacements will continue to erode U.S. IP owner's rights.
3. Domestic mechanisms such as Special 301 will be insufficient to meet the challenge.

For patent holders, the good news is that India, notorious for using compulsory licenses to control domestic drug prices, recently denied a compulsory license to a local Hyderabad company, Lee Pharma, for Astra Zeneca's patented drug Saxagliptin, used in diabetes management. The controller for the Indian Patent Office in Mumbai expressly found that Lee Pharma had failed to establish that the drug was not "reasonably available" in light of reasonably priced alternatives and a proposed pricing structure that frankly did not carry Lee Pharma's alleged 300 percent production savings claim forward to the public.

More international organizations, such as the World Health Organization and United Nations, are formally recognizing the important role that patents play in developing new medical treatments. This is in marked contrast to a decadeslong history of treating patents as problematic barriers to the human right to health.

Paradigmatic of this new recognition is a draft declaration on "Science, Technology and Innovation Development" before the U.N. General Assembly offered by Ecuador. The declaration underscores the critical role a "balanced and effective intellectual property framework" plays in fighting diseases (among other global challenges).

Unfortunately, however, this recognition is couched in terms of creating a development environment that supports "social responsibility" and "balanced" rights. These terms are usually code words internationally for crafting protection systems that allow greater access to technology with limited, if any, compensation to the patent holder.

More problematic, even if India appears to have temporarily abandoned an aggressive compulsory license regime, Germany granted its first provisional compulsory license for Isentress, containing the patented ingredient raltegravir, for the treatment of HIV.

In addition, the WHO recently issued reports advocating greater transparency in delivered pricing. Even the patent committee of the World Intellectual Property Organization is considering the removal of linkage requirements between patents and marketing approvals.

In its current form the WIPO draft cites exceptions under Hatch-Waxman for generic drug approvals as an example of positive delinking. There is no guarantee, however, that future drafts will remain so constricted in their favored exceptions. To the contrary, WIPO's recent report on Intangible Capital in Global Value Chains has further heightened scrutiny of the impact of patents, pricing transfers and even branding on international access to a wide variety of goods, including pharmaceuticals and technology.

Finally, the European Union and numerous countries, including China, South Africa and to a certain extent, the United States, are considering the impact of competition laws on the regulation of pharmaceutical access and pricing. In particular, renewed focus on the application of "abuse of monopoly" prohibitions to combat pricing and access problems promises that this intersection between trade regulation and IP will remain "hot" in 2018.

For trademark owners, the complexities of Brexit and its impact on both U.K.- and EU-registered rights, remains uncertain. In September, a position paper by the European Commission Task Force for the Preparation and Conduct of the Negotiations with the United Kingdom signaled a desire by the EU to assure continued protection for "intellectual property rights having a unitary character."

Included within the scope of such IP rights are EU-registered trademarks, registered and unregistered community designs and "geographic indications, protected designations of origin and other protected terms," or GIs, in relation to agricultural, foodstuffs and spirits. The position paper, unfortunately, is short on recommendations for how to achieve such protection.

Although the future treatment of U.K.-based "unitary character rights" currently protected as a result of EU membership should be part of a negotiated agreement regarding continued protection of such rights, there is no indication or recommendation in the paper concerning such protections.

Worse, the strong focus on securing continued protection for EU-based GIs may signal a stumbling block in the already fraught Brexit negotiations. Given the economic reasons cited for the U.K.'s exit from the EU, it is doubtful Prime Minister Theresa May's government would be willing to provide British support for what are essentially EU agricultural price supports.

Based on these developments, if you have not already considered parallel registrations in both the EU and the U.K. to secure trademark and design protection, you should place the issue in red ink at the top of your to-do list.

consideration exceptions and limitations related to libraries, archives and educational institutions, research and teaching, broadcasting, and museums.

In addition, the debate over the precise application of the exceptions contained in the Marrakesh Treaty governing access to copyrighted works for the visually impaired is rapidly devolving into a debate over the extension of fair use rights for a wide range of disabilities, and other potentially non-commercial uses, without protections against the increase in digital piracy that widespread unfettered access could present.

For all IP owners, studies such as the WHO's 2017 report on Fake Medicines increasingly recognize the virtually intractable nature of the global piracy problem. Yet there are no current efforts to create new international accords to deal effectively with the issue.

With the American retreat from international obligations that provide critical enforcement infrastructure, including the TPP, NAFTA and other U.S. trade agreements, and its practical withdrawal from WTO dispute settlement processes; the United States has left future enforcement structures in the hands of countries that do not favor strong IP rights protection.

To the contrary, former enforcement mechanisms are increasingly being replaced by programs similar to those in China that emphasize "self-sufficient, indigenous innovation" and strengthening the country's capacity "to transform innovations into intellectual property through original innovation … and secondary innovation based on imported technologies."

As I indicated in an earlier column (June 12, 2017), complacency in the face of these developments does not bode well for U.S. IP owners.

Without the necessary infrastructure, the U.S. will be forced to deal with these issues on a costly, country-by-country basis, similar to its current efforts to curb such practices in China through a Special 301 process. Such country-by-country actions are costly, slow and require government expenditures at a time of increasing budget deficits. Their effectiveness as the sole tool the United States can use in combating these global challenges is doubtful at best.

Vigilance and proactivity are required for 2018. Select those issues that have the greatest potential to affect your interests and monitor them with a view to taking a proactive role as needed before both relevant U.S. agencies, such as the U.S. Patent and Trademark Office and the U.S Trade Representative and international organizations, including WIPO, WHO and the WTO. Placing international developments on the back burner, unfortunately, is no longer an option.