HUMANITARIAN CLAUSES IN U.S. TECH TRANSFER LICENSES AND INDIA’S ROLE IN THE WORLDWIDE GENERICS INDUSTRY

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ABSTRACT

Human rights advocacy groups in the U.S. have pushed university tech transfer offices to include so-called “humanitarian clauses” in exclusive licenses for diagnostics and therapeutics to industry. These clauses generally allow the licensee to have exclusivity in developed countries, but not in undeveloped ones. Because universities increasingly own many of the key patents to critical medicines, the hope is that widespread use of such clauses will significantly reduce the possibility that patents are blocking the distribution of these medicines in impoverished countries. The problem is that many of the most needy countries have no infrastructure to produce medicines even if there were no restrictive patent or other rights. Accordingly, better developed nations like India have provided a crucial mediating role by producing affordable quality generic versions of these medicines for distribution in developing nations. Yet, as India strengthens its IP laws, particularly in the context of international treaties such as TRIPs, its generic pharmaceutical manufacturers will need specific permission from patent owners to continue such distribution. At the same time, the pharmaceutical patent owners or exclusive licensees will be reluctant to permit production of generics during the life of the patent in countries such as India, because those generics might well wind up in the Indian market, and other developed markets, rather than just in the needy countries. This paper will consider the challenges to U.S. tech transfer offices in crafting humanitarian clauses in their exclusive licenses to industry that allow generics production during the patent term solely for distribution in truly needy countries.

I. What Are Humanitarian Clauses?

The term “humanitarian clauses” in the intellectual property (IP) and technology transfer (tech transfer) fields generally designates any provisions in IP license agreements that limit the scope of an otherwise exclusive license grant to a drug patent for the purpose of allowing the claimed drug to be freely manufactured and distributed for use in poor countries. That is, the licensee must consider his license to patents around the world in an agreement containing a humanitarian clause to be exclusive only to the extent that the patents are practiced to manufacture or distribute products to developed markets that can afford them. His license is essentially non-exclusive where the patents will be
practiced to manufacture or distribute products to poor developing markets that cannot afford to pay full price for them.

There is no universally accepted definition for the term “humanitarian clauses,” however, so IP agreement provisions that are deemed to be such clauses by the parties to the agreement may contain only some of the features described above. Nonetheless, I believe that the description captures the full purpose and intent behind robust humanitarian clauses. Further, this robust version aligns well with the stated goals of groups like Universities Allied for Essential Medicines (UAEM)\(^1\) who have been strong proponents of the use of humanitarian clauses.

To date, a number of private U.S. universities like Yale and public U.S. universities like the University of California at Berkeley have either included humanitarian clauses in some exclusive tech transfer agreements or are seriously considering doing so. Whether this use is based on truly objective assessments of the clauses value, or is primarily a response to public pressure from groups such as UAEM remains to be seen. It may be that university tech transfer offices are skeptical of the real value of the clauses, but at the same time believe that they will do little harm even if they have no practical benefit.

A more aggressive form of humanitarian clauses is that which not only limits exclusivity, but also requires the licensee to actually play a role in ensuring that low or no cost drugs are made available under the patent license to poor developing countries. In practice, this version will clearly be harder for tech transfer offices to include in deals with licensees. Indeed, any insistence on the incorporation of such a clause – or even regular humanitarian clauses – in a proposed agreement might jeopardize the chances of the deal being executed at all.

II. The Global Pharmaceuticals Market

A. The Role of University Tech Transfer

So far, we have been talking about universities as patent owners and potential users of humanitarian clauses in tech transfer agreements. Many other organizations and individuals hold drug patents, of course, so why focus on universities? The answer is that universities – especially public universities in the U.S. – may well have, or be perceived to have, social welfare obligations that make them particularly susceptible to social and political pressure to either actively work for the greater good, or at least to not engage in activities that facilitate hardships in the world. Later, we will consider whether these social welfare obligations reach only to a university’s local or regional community, or whether they extend to national or even global communities.

There is a further reason to focus on universities for the deployment of humanitarian clause: many of the world’s pioneering drugs continue to be discovered in

\(^1\) http://www.essentialmedicine.org/.

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U.S. university research labs. Thus, even as pharmaceutical companies in countries such as India have become powerful players in the global generic pharmaceuticals market, research organizations in the United States appear to retain the lead in developing the original or pioneering version of blockbuster drugs. Most importantly, ownership of exclusive patent rights on blockbuster drugs generally lies with the research entity that created the pioneering version – not the generics companies who create follow-on bioequivalent versions – and hence the pioneer patent holders can exercise substantial control of the market place for the drug during the term of the patent. In fact, the U.S. Bayh-Dole Act\(^2\) gives universities title to patents on these drugs even if federal funding was used to fund all or part of the research leading to the drug’s invention.\(^3\) Thus, U.S. universities, with their dual role as creators and owners of major publicly and privately funded innovations, are easily one of the preeminent forces in the worldwide global pharmaceuticals market.

Within U.S. universities, tech transfer offices administer the university’s patents. The tech transfer office has near total control of the university’s patent portfolio and can choose to whom it wants to grant licenses and under what conditions. However, if federal funding was involved, even in part, to create the patentable invention, then the Bayh-Dole Act requires the university to effectively commercialize the patent, on pain of the original funding agency “marching in” to grant a license to the patent to a third party for commercialization.\(^4\) Further, the Bayh-Dole Act requires the university to grant the U.S. government a non-exclusive license to the patent for use by or on behalf of the government as condition of federal funding of the research leading to a patentable invention.\(^5\) Thus, these two conditions provide an important hedge against the otherwise exclusive control of universities and their tech transfer offices over federally funded pharmaceutical inventions. Nonetheless, tech transfer offices may still grant what are deemed exclusive licenses – really exclusive commercial licenses – to federally funded inventions to private manufacturing companies largely at the tech transfer offices’ sole discretion. In the case where no federal funding is involved, and absent any other restrictions arising from other funding sources, tech transfer offices are generally free to decide to whom they want to grant licenses and indeed to withhold licenses entirely if they so choose.

B. The Role of Patents

Patents are powerful, but territorial – a patent is generally only enforceable in the jurisdiction in which it was issued.\(^6\) International agreements, such as the Patent


\(^{3}\) Faculty ownership of patents arising from the faculty member’s own research in the university lab is exceedingly rare as nearly all universities require faculty members to assign such patentable inventions to the university. In other words, there is generally no “professor’s privilege” in the United States with regard to patentable inventions. Professors do generally retain copyright to copyrightable subject matter that they create as part of their faculty appointment however.


\(^{5}\) 35 U.S.C. § 202(c)(4).

\(^{6}\) Patents can have a kind of extraterritorial impact when, for example, a jurisdiction prohibits the importation of goods embodying the patent, or manufactured by the patented method, even where the
Cooperation Treaty (PCT), have made it easier for patentees to obtain patents across multiple jurisdictions, but the patentee still needs to intend to seek patent protection in those jurisdictions – there is no global patent covering all jurisdictions around the world. Accordingly, if patent protection for a pioneer drug is not obtained in a given jurisdiction, such as a very poor undeveloped country, then the owner of the patent to that drug in other countries, such as wealthy developed nations, has no legal ability to prevent manufacture or distribution of the drug in the poor nation.

In fact, pharmaceutical companies do not necessarily seek patent or license rights in every country in the world. This would be costly and inefficient. In some countries there is either no real patent law to speak of, or that which is on the books is not enforced. In other countries, there is simply not enough of a market of individuals or organizations who are able to afford the drugs at prices that would make it worthwhile for the pharmaceutical company to pay patent issuance and maintenance fees, on top of the costs to manufacture and distribute the drug to that market. Thus, it is a truism in the pharmaceutical industry that the main focus for patent protection is the “big three” markets: the U.S., Europe, and Japan. Accordingly, the overwhelming amount of drug patent filings are in the U.S. Patent & Trademark Office (USPTO), the European Patent Office (EPO), and Japanese Patent Office (JPO). Applications for patents will be filed in other jurisdictions on a case-by-case basis based upon factors such as the cost effectiveness of a particular drug’s manufacture, distribution, and sale in or for that market, or the risk that generic drug manufacturers in that jurisdiction will manufacture copies of the drug for distribution to markets where the pioneer company hopes to make substantial profits.  

At the same time, because U.S. university tech transfer offices are primarily seeking to license new drug inventions out to the pharmaceutical companies for commercialization, they have little interest in obtaining patent protection for the inventions outside of the U.S. until or unless a potential or actual licensee requests such protection. Even then, the tech transfer office will likely require the licensee to pay for whatever application and maintenance fees arise from the additional filings in foreign jurisdictions.

Thus, in the end, there are numerous situations where patents are not any kind of obstacle to the distribution of essential medicines in poor countries. In the most undesirable markets, there is often no patent sought, or enforceable, for key drugs. The problem instead is that the country has no infrastructure capable of manufacturing and distributing the drugs. Therefore, the country is totally reliant on companies in other nations to manufacture and distribute essential medicines to it. It is to these countries,
India preeminent among them, that we turn now to trace the path of affordable medicines for poor countries.

C. The Role of India

India is one of the major generic drug producers in the world and it has been especially important in supplying affordable generics to some of the poorest countries in the world. Even with this supply, however, and including other humanitarian aid sent to these countries from wealthier nations, sadly the high levels of government corruption and chaotic warring conditions among tribal warlords in these poor countries siphon off much of this largesse before it is distributed to the impoverished citizens who really need it. At the same time, some of the affordable generics supplied by India and other middle producers to these poor countries will instead find their way through gray market channels to more affluent countries. Similarly, there is concern among U.S. and European pharmaceutical manufacturers that generic versions of their drugs produced legally in India are being directly, yet improperly, shipped back to the U.S. and Europe to undercut the prices that those companies charge patients there.

Much of the Indian manufacturers’ ability to supply grey market drugs to affluent countries against the pioneer companies’ wishes (and legal patent rights) has been based on relatively weak IP laws and enforcement in India. Yet, now that the Indian Patent Act of 2005 offers the promise of stronger and better enforced patent laws in India, one might wonder whether this will in fact restrict the freedom of Indian generics manufacturers to supply unauthorized versions of pioneer drugs still under patent to the gray market. If it does, this may be good for pioneer drug companies in the U.S. and Europe, as well as the patent holders, such as universities, in those regions. But, it could well be very bad news for sick people in poor countries who may no longer be able to rely on quality, affordable generic drugs supplied by Indian companies.

III. The U.S. University Tech Transfer Office and the Generics Market

A. The Mission of the U.S. University Tech Transfer Office

Most U.S. tech transfer offices do not have a clear unitary mandate as to their mission. Rather, they are often given conflicting and sometimes mutually exclusive goals and objectives by the central administration on campus. The three major missions usually charged to tech transfer offices, separately or in some combination, are: maximize returns on university inventions; disseminate knowledge to the worldwide scientific community; and aid local or regional economic development. Maximizing return on inventions likely requires exclusive licenses that in turn generally work against broad free dissemination of scientific knowledge. Aiding local or regional economic development may require exclusive licenses at less than full market value to local companies instead of highest bidder value licenses to multinational corporations, which in turn means that the maximum economic return on the university’s inventions is not
being returned. Accordingly, tech transfer offices cannot effectively pursue all three missions simultaneously.

Yet, if the central administration on campus is unwilling to charge the tech transfer office with a particular mission, or set of missions, then how should the offices decide which mission takes precedence in deciding how to license a particular invention? The answer for many U.S. tech transfer offices seems to be that they simply either try to simultaneously pursue all three missions, or, given the likely impossibility of that in all but the rarest situations, they may try to generate the appearance that they are simultaneously fulfilling all three missions. In other cases, they may decide that they need to choose which mission takes precedence on a case-by-case basis, e.g., maximizing revenues on one deal, while achieving broad free dissemination of new scientific knowledge in another.

B. University Tech Transfer Offices Can Exercise Some Control Over the Global Generics Market

Tech transfer offices can attempt to inject novel deal provisions into tech transfer license agreements if they wish. Ideally, such clauses would further at least one of the standard missions set out above. Thus, tech transfer offices undoubtedly have the ability to add humanitarian clause to some or all of their proposed licenses to drug companies. Further, because tech transfer offices in the aggregate effectively control much of the pioneer drug invention pipeline, they could have a substantial impact on the global generics market by collectively insisting on humanitarian clauses in all major pioneer drug licensing deals.

Tech transfer offices could also affect the global generics market by choosing to license key new drug inventions only to drug manufacturers who commit to producing and distributing affordable versions of essential medicines to needy patients either only in poor developing countries or even in developed countries as well. This could be as effective as employing humanitarian clauses in licenses with manufacturers who were not interested in distributing affordable medicines to needy patients, because in this latter case, the tech transfer office need rely on some third party generic drug manufacturer to pick up on the lack of exclusive rights to the licensee for production and distribution of drugs to needy patients. Yet, with no incentive of exclusivity in affluent markets, and with the disincentive that the university or exclusive licensee might still attempt to sue it for infringement, the third party manufacturer might well choose to steer clear of the cost of ramping up production of the particular drug.

Finally, tech transfer offices could also alter the global generics marketplace by putting key new patentable drug inventions into the public domain through either publication or the U.S. statutory invention registration process. Because most countries have no grace period for patent applications to be filed after public disclosure of the invention, such a move would effectively extinguish the possibility for exclusive patent rights to anyone across much of the globe. But in the absence of such exclusive patent rights, and thus the lack of exclusive licenses thereunder as well, drug manufacturers may
well lack any meaningful incentive to incur the expense of ramping up production and
distribution of new essential medicines. In the end, the best model might not be
humanitarian clauses or the deposit of the invention into the public domain, but rather a
difference kind of socially responsible licensing that requires the licensee to shoulder its
fair share of the burden of caring for the world’s poor.

C. Do Humanitarian Clauses Advance the Missions of the U.S. Tech Transfer Office?

To gauge whether humanitarian clauses become widespread, one must determine
whether they advance the tech transfer offices’ mission(s) in any meaningful way. Of
course, this means that we must know what the tech transfer office’s mission is, when in
fact, as seen above, we generally do not know. If the tech transfer office’s mission is to
disseminate information, or perhaps even advance human welfare generally, then
humanitarian clauses probably do advance this mission. If the mission is to maximize
returns or facilitate local or regional economic development, then the use of humanitarian
clauses probably does not advance these missions. The more challenging scenario occurs
when the tech transfer office has a combined mission, or simply one that is too
indeterminate to tell. To the extent that we do not know the office’s mission, then we
will be unable to speculate intelligently about the likelihood that it will use humanitarian
clauses.

IV. The Challenges of Humanitarian Clauses

Ideally, humanitarian clauses would only restrict exclusive licenses in
underdeveloped nations, to the extent that any patent rights are obtained in those nations
in the first place. However, most of these countries lack the manufacturing infrastructure
to produce affordable generics, regardless of any restrictive patent rights. Thus, other
countries such as India have been producing low cost generic drugs for distribution in poor
countries. As India strengthens its IP regime, however, its generic drug manufacturers
will have to obtain legitimate rights to drug patents still under term. Therefore,
humanitarian clauses will have to permit manufacture of generics even in up and coming
countries such as India.

At the same time, pioneer drug companies may balk at paying for an exclusive
license that will allow other companies to manufacture generic versions of the drug in
important developing markets such as India. Further, the pioneer drug companies may
also fear that these generics will flow through the grey market back to the U.S. and other
major developed markets as well. Obviously, the answer is for humanitarian clauses to
only allow third party companies to manufacture generics for distribution to truly needy
countries or patients. The question is whether these generics distribution limitations will
be respected and enforced. If not, then the risk will likely prove too much for pioneer
drug companies and they may choose to forego the license altogether.
Bibliography


Sean M. O’Connor,

The Use of MTAs to Control Commercialization of Stem Cell Diagnostics & Therapeutics, 21 BERKELEY TECHNOLOGY LAW JOURNAL 1017 (2006)
