Reservation of Rights for Humanitarian Uses

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ABSTRACT

An explicit reservation of rights in a commercial technology license can ensure that the licensor's institutional objectives to support humanitarian applications of its technology are not inadvertently blocked or sidetracked by overly broad terms in the commercial license. Many universities routinely use a reservation of rights to guarantee continued use of licensed technologies within the ongoing research or educational programs of the university. Clauses included in license agreements to reserve rights for humanitarian use of technology are still rare, but awareness is increasing of the utility and importance of such clauses, particularly as philanthropic-research sponsors begin to require grantees to ensure that results and discoveries will be made available for humanitarian purposes. The structure of a clause to reserve rights for humanitarian use ideally both expresses the philosophical intent of the licensee and clearly defines the boundaries of humanitarian use, particularly in relation to commercial use.

1. INTRODUCTION

The reservation of certain rights in commercial license agreements is a means for the technology provider (the licensor) to declare its explicit intent to reserve or retain certain rights over the technology—to not grant those rights under the license—in order to help ensure that the terms of the license will not block other specific goals that the licensor may have. Such goals are typically noncommercial and therefore do not directly impair the licensee's ability to commercialize the technology, but they may be important to ensure that the licensor can continue to meet other institutional objectives such as education, research, and public service. In the case of university research, this typically includes the goal of ensuring that future noncommercial research is not blocked and, increasingly, that humanitarian uses and applications of the technology are not blocked.[1] This chapter will briefly address a single issue—that of creating an explicit reservation of rights in a commercial technology license to ensure that institutional objectives to support humanitarian applications of its technology are not inadvertently sidetracked by an overly broad commercial license. Furthermore, the regular use of this type of *reservation-of-rights* clause provides a means to regularly articulate an institution's commitment to manage technologies for the broadest public benefit.

2. RESERVATION-OF-RIGHTS CLAUSE

License agreements broadly define the terms under which a technology provider (licensor) will transfer intellectual property and/or tangible property to a technology user or developer (licensee), usually for commercial development. In many cases, the license agreement is nonexclusive or it carefully defines the use of the technology for a specific field or a specific geography. In such cases, the licensee does not grant—but

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instead retains—rights to the technology in all areas other than those defined within the scope of the license, and therefore a specific reservation of rights may not be necessary. However, for some technologies and in some technology sectors—including biotechnology—broad exclusive licenses are often required to induce follow-on investment in research and development. In these cases it can be important for the licensee to explicitly reserve rights to ensure that its noncommercial institutional objectives are not blocked by the exclusive terms of the commercial license.

For example, universities frequently incorporate a clause that reserves rights to carry on research using licensed patents and/or technology. This has become increasingly important since the *Madey v. Duke University*[2] ruling effectively narrowed, beyond any practical use, the research exemption codified in U.S. patent law for university research.[3] This lack of a research exemption in the United States has created the unusual situation where a university invention, if licensed exclusively, may be unavailable for ongoing research even in the very laboratory where the invention itself was made. To address this situation, many universities in their exclusive license agreements now reserve rights for the use of inventions within their own institution or, even more broadly, within all academic or nonprofit research institutions.

The University of California and Stanford University routinely incorporate clauses into their exclusive license agreements (Box 1). This type of reservation-of-rights clause is perhaps the most common type used in university license agreements, although even this straightforward and reasonable term still is not used by many universities in their exclusive license agreements.

Clauses in university license agreements that reserve rights for humanitarian use of the technology are an exception, rather than a rule, but awareness of the utility and potential importance of such clauses is increasing. Today there are examples of research sponsors and programs—such as philanthropic foundations—that require grantees to ensure that research results and discoveries will be made available for humanitarian purposes. Based on this type of sponsor requirement, grantees who execute a commercial license to any technology developed under the research agreement would thus be required to include a clause that acknowledged this existing obligation and reserved rights for humanitarian purposes.

3. THE STRUCTURE OF A RESERVATION OF RIGHTS

A reservation of rights for humanitarian uses can be a very simple statement expressing the philosophical intent of the licensee. For example, at the Donald Danforth Plant Science Center all research and license agreements include a statement that the "*Company and Danforth Center shall diligently and in good faith negotiate the terms of a worldwide license, making provision for preserving*

Box 1: Sample Reservation of Rights in Exclusive Licensing Agreements

The University of California

Nothing in this Agreement will be deemed to limit the right of The Regents (the University)... to make and use the Invention ... and associated technology and allow other educational and nonprofit institutions to do so for educational and research purposes.

Stanford University

Stanford retains the right, on behalf of itself and all other nonprofit academic research institutions, to practice the Licensed Patent and Technology for any purpose, including sponsored research and collaborations. Licensee agrees that, notwithstanding any other provision of this Agreement, it has no right to enforce the Licensed Patent against any such institution.

the availability of the intellectual property (IP) for meeting the needs of developing countries."[4] While this has the advantages of being simple and ensuring that the licensee is on notice with regard to the intention of the licensor, the statement may not provide sufficient definition of "*meeting the needs of developing countries*" for the licensor to assess the extent to which this statement may affect its commercial markets. As a consequence, more elaborate clauses have been crafted in efforts to clearly define the boundaries of humanitarian uses, particularly in relation to commercial uses.

3.1 *Definitions*

The definitions are the most critical component of a reservation of humanitarian use rights. The key definitions are:

Humanitarian purposes. There are several approaches used to define humanitarian purposes: by income level, by uses (subsistence or commercial), and by geography. Each approach has its own set of limitations. Using a definition that equates *humanitarian uses* with *subsistence uses* has been adopted for some agricultural applications but will probably not be applicable in the health sector, since few technology applications can be achieved without significant investment by a commercial partner (this is becoming increasingly true in agricultural innovations as well). Where subsistence uses are part of the definition, it may be important to define income levels of the subsistence "users." This criterion has been applied in the case of the humanitarian license for Golden Rice[5] but could raise difficult practical issues for compliance or monitoring. Alternatively, *humanitarian uses* can be defined geographically by specifying all uses of the technology within developing countries.

Developing countries. If *humanitarian uses* is defined geographically then an explicit definition of *developing countries* is needed. For example, *developing countries* can be defined as those listed by the World Bank or other international agencies. While this definition can effectively segment the commercial and humanitarian uses of a technology, the current lists of developing countries may not capture the entire set of desired geographies. Such a definition should have flexibility to allow the expansion of the geographical list. In addition, if such a geographical definition of humanitarian uses is used, then the issue of use and sales outside of this defined territory should be explicitly addressed.

Commercial purposes. Because the reservation of rights for humanitarian uses is designed to be used in the context of a commercial license and, specifically, to segment the markets for a technology between commercial and humanitarian uses, it may be important to define the scope of commercial uses as well.

3.2 *Reservation of rights*

The reservation of rights is the operative paragraph of the clause, and its structure will rely upon and follow the above definitions. The reservation of rights needs to clearly articulate what rights are being reserved and should leave no doubt that the reserved rights may be granted to other appropriate companies or organizations that can fulfill the humanitarian objectives. This may be a topic of discussion in license negotiations, largely because it is likely to be an unfamiliar term to a commercial licensee.

4. STANDARD CLAUSES

There are relatively few examples of standardized reservation-of-rights clauses, because they are likely to be crafted individually to meet specific situations. However, as an object lesson, here are two examples, one developed for agricultural technology licenses and one developed for health technology licenses.

The Public Intellectual Property Resource of Agriculture (PIPRA) has crafted a standard reservation of humanitarian-use-rights clause that encourages its members to include in commercial licenses for agricultural technologies, particularly in exclusive licenses. The clause (Box 2) may serve as a model or starting point for similar license clauses that seek similar objectives.

The Office of Technology Licensing at the University of California, Davis crafted a reservation-of-rights clause intended for a commercial license of a health technology (Box 3). Likewise,

Box 2: PIPRA's Reservation of Rights for Humanitarian Uses

Definitions.
"Humanitarian Purposes" means (a) the use of Invention/Germplasm for research and development purposes by any not-for-profit organization anywhere in the World that has the express purpose of developing plant materials and varieties for use in a Developing Country, and (b) the use of Invention/Germplasm for Commercial Purposes, including the use and production of Germplasm, seed, propagation materials and crops for human or animal consumption, in a Developing Country.
"Commercial Purposes" means to make, have made, propagate, have propagated, use, have used, import, or export a product, good or service for the purpose of selling or offering to sell such product, good or service.
"Developing Country" means any one of those countries identified as low-income or lower-middle-income economies by the World Bank Group at the time of the effective date of this agreement and all other countries mutually agreed to by Licensor and Licensee (the current list of countries is typically given in an appendix to the agreement).[6]

Reservation of rights.
Notwithstanding other provision of rights granted under this agreement, University hereby reserves an irrevocable, nonexclusive right in the Invention/Germplasm for Humanitarian Purposes. Such Humanitarian Purposes shall expressly exclude the right for the not-for-profit organization and/or the Developing Country, or any individual or organization therein, to export or sell the Germplasm, seed, propagation materials or crops from the Developing Country into a market outside of the Developing Country where a commercial licensee has introduced or will introduce a product embodying the Invention/Germplasm. For avoidance of doubt, not-for-profit organization and/or the Developing Country, or any individual or organization therein, may export the Germplasm, seed, propagation materials or crops from the Developing Country of origin to other Developing Countries and all other countries mutually agreed to by Licensor and Licensee.

Box 3: Reservation of Rights for Humanitarian Use: University of California, Davis

1.40 "Humanitarian Purposes" means (a) the use of Licensed Products covered under Compound Patent Rights ("Compound Products") for research and development purposes by any organization or other third party, anywhere in the world that has the express purpose of developing the Compound Products for use in an Economically Disadvantaged Country, and (b) the use of the Compound Products by any organization or other third party for Commercial Purposes in an Economically Disadvantaged Country.

1.41 "Commercial Purposes" means to make, have made, use, have used, import, or export a product, good, method, or service for the purpose of selling or offering to sell such product, good, method, or service.

1.42 "Economically Disadvantaged Country" ("EDC") means all countries listed on the United Nations Conference on Trade and Development list of "Least Developed Countries" in effect as of the Effective Date of this Agreement which are set forth on Appendix I hereto.

2.14 In any license to the Licensee, Licensee's commercial use of the Compound Patent Rights to make, use, sell, offer for sale and import Compound Products in EDCs will be royalty free and the Licensee will be required to give away the Compound Products for free or at cost.

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it may serve as a model or starting point for similar license clauses that seek such an objective.

5. CONCLUSIONS

It has recently been suggested that national public policy guidance is needed to support measures that require that publicly funded research results be managed in a way that preserves the opportunity to mobilize new technologies to meet humanitarian needs of the world's poorest people in addition to meeting the commercial needs of the developed world.[7] In the absence of such national policies, voluntary measures can still be taken to ensure that research results, new discoveries, and patented inventions are not unnecessarily blocked from serving humanitarian purposes and meeting the needs of the world's poor. For public research institutions, a reservation of humanitarian rights in commercial technology licenses is one mechanism to help it meet its mission to serve the public benefit through both commercial and humanitarian channels. ■

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1 The broader topic of humanitarian access to health and agricultural innovations and a discussion of strategies to ensure broader access are also addressed in this *Handbook* in various chapters, most notably chapter 2.2 by AL Brewster, SA Hansen and AR Chapman. For specific aspects of the topic, see in this *Handbook*, chapter 12.1 by RT Mahoney.

2 (307 F.3d 1351 [Fed. Cir. 2002]) .

3 Ludwig SP and JC Chumney. 2003. No Room for Experiment: The Federal Circuit's Narrow Construction of the Experimental Use Defense. *Nature Biotechnology* 21:453.

4 Beachy R. 2003. IP Policies and Serving the Public. *Science* 299:473. See also in this *Handbook*, chapter 17.10 by K Schubert.

5 Brewster AL, AR Chapman and SA Hansen. 2005. Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation. *Innovation Strategy Today* 1(3):203-216. www.biodevelopments.org/innovation/index.htm.

6 web.worldbank.org/WBSITE/EXTERNAL/DATASTATISTICS0,,contentMDK:20420458~menuPK:64133156~pagePK:64133150~piPK:64133175~theSitePK:239419,00.html. Last updated by the World Bank July 2006.

7 Boettiger S and AB Bennett. 2006. Bayh-Dole: If We Knew Then What We Know Now. *Nature Biotechnology*. 24:320–24.

Box 3 (continued)

2.15 Notwithstanding other provision of rights granted under this Agreement, The Regents [the university] hereby reserves the right to license the Compound Patent Rights to any third parties for solely Humanitarian Purposes. Such licenses for Humanitarian Purposes will expressly exclude the right of the third party licensee to export or sell the Compound Products from an EDC into a market outside of the EDC where Licensee has introduced or will introduce a Compound Product and where Patent Rights exist. In any such license, the third party licensee's commercial use of the Compound Patent Rights to make, use, sell, offer for sale and import Compound Products in EDCs will be royalty free and the third party licensee will be required to give away the Compound Products for free or at cost. For avoidance of doubt, the third party licensee may be permitted to export Compound Products from the EDC of origin to other EDCs and all other countries mutually agreed to by The Regents and Licensee.