Appendix B

Patent Rights and Other Intellectual Property Rights
PATENT RIGHTS AND OTHER INTELLECTUAL PROPERTY RIGHTS

Although it’s not known that patent rights are currently impeding progress in vaccine development, there is a good possibility that they may. Patented methods are often profitable to the company owning the patent.¹ For this very reason, patent rights could create a financial barrier to the easy sharing of methods between companies—for example, sharing the best methods of producing a vaccine or enhancing its potency.²

Biotechnology expert Edward Hammond has noted the possibly enormous value of patented discoveries in the event of a pandemic:

The ultimate value of the currently claimed sequences [of the influenza virus gene and parts of the gene] and technologies is uncertain, but if any prove critical to combat a pandemic, it may be enormous. If a particular sequence, adjuvant or cell culture process is uniquely advantageous to producing an effective pandemic vaccine, then access to that technology may be mandatory for protection of public health. With the dramatic upswing in patent activity, these concerns will steadily increase.³

The government should urge vaccine manufacturers to loosen their grip on their own patented methods, as well as on their trade secrets and know-how. In selected cases, manufacturers should be pressed to give other companies quick access to these methods, free of charge or at low cost, instead of charging their usual licensing fees or royalties or blocking access altogether.

In a previous time of crisis, one company took a decisive step to eliminate questions about its patent rights. During World War II, the DuPont Company insisted on surrendering all patent rights arising from its involvement in the Manhattan Project. “The importance to the nation of

¹ Many patents are never used and of those that are used, only a few prove profitable.

² A limited vaccine supply can be expanded several-fold simply by the addition of adjuvants—substances that enhance the potency of small doses of certain common types of vaccine. Patented proprietary adjuvants are now being tested and used by federal government contractors. To maximize the chances of success of the government’s vaccine program, licensing fees and royalties should not be allowed to stand in the way of any company, with or without a government contract, that wants to test and use another company’s patented adjuvant. Also, patent rights should not be allowed to hinder direct head-to-head comparisons of the most promising adjuvants.

Several companies presented results of their clinical studies on flu vaccines at a meeting in February 2007 sponsored by the World Health Organization. Three companies included their own proprietary adjuvants in some of the vaccines they tested. None compared their own adjuvants with the proprietary adjuvants controlled by the other companies. The studies are described in the presentation documents for this meeting: World Health Organization. “3rd WHO meeting on evaluation of pandemic influenza prototype vaccines in clinical trials, 15-16 February 2007, WHO, Geneva.” www.who.int/vaccine_research/diseases/influenza/meeting_150207/en/ (Downloaded February 14, 2008).

the work on releasing atomic energy was so great that control, including patent rights, should rest with the government,” wrote the president of DuPont.\(^4\)

One vaccine company has already moved in this direction. In December 2003, MedImmune, Inc. relaxed its control over a unique method of crucial importance to the production of influenza vaccine. MedImmune made its patented method (“reverse genetics”) available without charge to any company using the method for non-profit, public health purposes in developing vaccines for pandemic influenza.\(^5\)

Federal government officials should publicly applaud this kind of corporate generosity when it occurs.\(^6\)

Sometimes just the threat of a compulsory license imposed by the U.S. or other countries will induce a company to loosen its patent restrictions or lower its prices. This happened with Tamiflu, a patented drug used to treat influenza, and with patented AIDS drugs sought by developing countries that could not afford the high prices of these drugs.\(^7\)

But voluntary action by companies will probably be uncommon. The federal government can then intervene. Under federal law, the government can issue a “compulsory license” that allows a company to use another company’s patented method under terms set by the government and


\(^6\) There’s a limit to MedImmune’s generosity. Companies that plan to sell vaccine may be charged for using MedImmune’s reverse genetics technology. MedImmune “will receive an upfront payment and has the potential to receive royalties on certain stockpiles or sales of other influenza products developed using the reverse genetics technology.” MedImmune press release. September 24, 2007. http://investor.medimmune.com/phoenix.zhtml?c=83037&p=irol-investornewsArticle&ID=1054747&highlight= (Downloaded February 14, 2008).

The prospect of payments to MedImmune may discourage some companies from making a commitment to manufacture pandemic flu vaccine that will be sold. This is because their vaccines may be made from reference strains created in WHO-affiliated laboratories using MedImmune’s reverse genetics technology.

without the consent of the patent owner. Economist James Love has analyzed and provided examples of compulsory licensing.\(^8\)

There is an obvious downside to this peremptory step: it may deter corporate investment and innovation in the future. For this reason the government should ensure that appropriate compensation is promptly paid to any company forced to give up its patent rights.

Government officials should openly consider the option of imposing compulsory licensing for certain key patents. Otherwise, the sudden start of a pandemic may make it clear that the best moment to remove a patent barrier has passed, and that the delay will cost lives.

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