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INTELLECTUAL PROPERTY

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OECD sets guidelines for genetic invention licenses

There is tension between guidelines and some TRIPs articles.

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ON FEB. 23, THE Organization for Economic and Development (OECD) Council adopted guidelines for the licensing of genetic inventions. See Guidelines for the Licensing of Genetic Inventions (OECD, Paris, 2006), www.oecd.org/sti/biotechnology/licensing. The guidelines present principles and best practices for intellectual property licenses directed to facilitating access to genetic inventions and increasing the dissemination of genetic information derived from those inventions.

Policies informing the principles and best practices include a need to stimulate research through assurance of an adequate return on investment for biotechnology companies; a desire to encourage research by a broad range of scientists, especially those not involved in the conception of fundamental genetic inventions; and a hope that low-income countries will be able to utilize such inventions to further development of a health care system. The stated policies are well-intentioned, and each appears both reasonable and reachable when considered alone. It is the concurrent pursuit of all three that raises issues, which are discussed below.

PATENT

On Dec. 14, 1960, a Convention on the Organization for Economic Co-operation and Development was signed in Paris. See www.oecd.org. It came into force on Sept. 30, 1961, and delineated the mission of the OECD: "(a) to achieve the highest sustainable economic growth and employment and a rising standard of living in Member countries, while maintaining financial stability, and thus to contribute to the development of the world economy; (b) to contribute to sound economic expansion in Member as well as non-member countries in the process of economic development; and (c) to contribute to the expansion of world trade on a multilateral, non-discriminatory basis in accordance with international obligations." OECD Convention, Art. I.

There are currently 31 member states to the OECD Convention, and the organization has active relationships with 70 other countries. The OECD is well-known for its country surveys and reviews; it attempts to lay the groundwork for multilateral agreements through the production of internationally agreed-upon instruments, decisions and recommendations. The OECD's governing body, the council, is made up of representatives from member states.

The Guidelines for the Licensing of Genetic Inventions were an outgrowth of an earlier OECD initiative. The OECD held a workshop in January 2002 directed to whether patents granted for genetic inventions, and resulting licensing practices, were unduly affecting access to information, products and services for researchers, clinicians and patients. See Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies (OECD, Paris 2002). Participants in the workshop found that IP systems were largely functioning as intended with respect to health care purposes. Innovation and the disclosure of information were being stimulated, and there was no evidence to suggest common licensing terms were undermining such objectives. A specific concern related to access to genetic-based, diagnostic tests, however, was identified. This concern served as a basis for the subject licensing guidelines.

Prominent provisions

In terms of principles and best practices, the guidelines are divided into five categories: "Licensing Generally," "Healthcare and Genetic Inventions," "Research Freedom," "Commercial Development" and "Competition." Under "Licensing Generally," principles B.1.A and B.1.C stand out. Principle B.1.A provides: "Licensing practices should foster innovation in the development of new genetic inventions related to human healthcare and should ensure that therapeutics, diagnostics and other products and services employing genetic inventions are made readily available on a reasonable basis." B.1.C provides: "Licensing practices should provide an opportunity for licensors and licensees to obtain returns from their investment with respect to genetic inventions."

The annotations provide further insight into the espoused principles and best practices. Annotation 1.14, for instance, states: "[T]he Principles encourage licensing practices that make available genetic inventions on a reasonable basis. In certain circumstances, such as in the cases of health crises or health emergencies, licensors or licensees may determine not to seek a financial return, thus determining to make the genetic invention available for free or at cost."

Two more notable principles and a best practice appear in the section on "Healthcare and Genetic Inventions." B.2.A provides: "Licensing practices should seek to strike a balance between the delivery of new products and services, healthcare needs, and economic returns." B.2.D states: "Licensing practices should encourage appropriate access to and use of genetic inventions to address unmet and urgent health needs in OECD member countries and non-member countries." And B.2.1 provides: "Rights holders should broadly license genetic inventions for research and investigation purposes."

The OECD readily recognizes that its adopted guidelines are bounded and controlled by existing international agreements. The primary implicated agreement is the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS, which came into effect on Jan. 1, 1995, is a

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comprehensive, multilateral IP agreement covering copyrights, trademarks, geographical indications, industrial designs, patents, layout designs of integrated circuits, trade secrets and test data.

The guidelines should be read in light of at least two different TRIPS articles: Art. 31 and Art. 39. The first concerns conditions under which a member country may impose a compulsory license; the second covers the treatment of proprietary testing data. Art. 31, provides: "Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder...the following provisions shall be respected:...(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time... (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization."

Art. 39 provides: "Members when requiring as a condition of approving the marketing of pharmaceutical or of agricultural chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

TRIPS Art. 31 provides rules for member states that have compulsory licensing regimes. Even in cases of a national health emergency, a state must typically give notice of the license to a patent holder, and it must provide adequate remuneration for it. A health emergency, in other words, should not provide one with a right to eradicate the value of a patent holder's invention. See, however, the Doha Declaration on the TRIPS Agreement and Public Health 5(b) and 5(c), adopted Nov. 14, 2001, which states that each member state has a right to determine the grounds upon which a license is granted. Although the "grounds" should be tied to "adequate remuneration" in Art. 31, the issue appears to be in dispute.

The guidelines do not explicitly run afoul of TRIPS Art. 31. There is an emphasis on providing "reasonable" access to technology on a "reasonable" basis. The annotation to the principles, though, raises a hope that companies will voluntarily offer genetic inventions at either cost or for free. Should one attempt to breathe life into the guidelines using the annotation, adherence to the TRIPS provision would be in question.

Tensions with TRIPS article

With respect to proprietary data, there appears to be a tension between the guidelines and TRIPS Art. 39, although, again, there is no explicit conflict. Art. 39 is clear in its protection of data submitted for marketing approval; many interpret it as a sui generis protection barring the immediate entry of generics into the subject market. This recognition of a company's right to maintain data secrecy is in contrast with the guidelines' best practice of "broadly licens[ing] genetic inventions for research and investigation purposes." Allowing researchers to broadly examine one's invention virtually assures that previously proprietary data will be independently generated. This scenario might undercut the intent of TRIPS Art. 39.

Noble objective of Principle B.2.A is easier said than done.

Principle B.2.A states that balancing economic returns and health care needs is a licensing goal. This is a noble objective, but it is easier said than done. Drug companies typically begin exploratory projects after an initial evaluation by their marketing research department. Based on projected market size, estimated market penetration and pricing analyses, the companies develop an annual sales model for an envisioned therapeutic. They select an annual peak sales target and do not start a project unless it is likely that the target can be reached.

The possibility of compulsory licensing for a therapeutic on less than favorable terms introduces substantial uncertainty into the annual peak sales equation. This is at least for two reasons: A discounting factor must be applied in view of potential lost sales to countries experiencing a health emergency; and provision of the therapeutic to one or more countries at a severely reduced price may ultimately result in global price reduction. With respect to a discounting factor, one would have to eliminate low-income countries from the sales equations; one might be wise to eliminate many middle-income countries as well. The overall effect on projections depends on the particular disease state considered, but an envisioned sales reduction of 10% or more seems reasonable based on country-by-country figures for pharmaceutical consumption.

Global price reduction might result due to a well-understood policy perspective: High- and middle-income countries generally do not want to subsidize health care for low-income countries. Despite assurances to the contrary, it seems incredible that politicians would not view a large, voluntary price differential as a subsidy. Such a view would immediately result in pressure on drug companies to globally lower prices on a specific therapeutic. An initial marketing analysis on a therapeutic subject to such pressures would have to indicate a projected sales margin reduced by 50% or more. (This is estimated from existing compulsory licenses for low-income countries that provide for royalties approximately 1/15th of typical biotechnology margins.)

In more concrete terms, though, into what does the effect on projected margins or sales translate? A peak sales projection is based on typical margins for biotechnology or pharmaceutical products. If there is a 50% margin reduction, one would have to project at least two times the target to satisfy minimally acceptable criteria for exploratory program launch. In other words, if a typical cutoff is peak annual sales of at least $500 million per year, a therapeutic with potential application to a health care emergency in a low-income country would have to have projected peak sales of at least $1 billion per year in high- and middle-income states. This substantially increased criterion might mean that certain diseases will receive little to no attention from those most qualified—researchers at major biotechnology/pharmaceutical companies.

The guidelines are based on important policies such as stimulating research and providing reasonable access to state-of-the-art health care for low-income countries. They expressly fall within boundaries set by international agreements, such as TRIPS. Issues related to TRIPS compliance and economic viability of the guidelines only arise if one attempts to incorporate understated rationales—such as providing genetic inventions to countries for free or at cost—into the presented principles or best practices. Under that scenario, one must worry whether the fundamental purpose of the guidelines has been undercut. NLJ