National Optical Astronomical Observatories (NOAO). The United Kingdom is contributing 25%, Canada 15%, and Brazil and Argentina are chipping in 2.5% each.

Chilean astronomers see membership in the Gemini consortium as a mixed blessing. On the one hand, they covet the chance to shape and benefit from a major new facility, and they regard Gemini as a shot in the arm for their discipline. "Gemini represents a chance to go from being a spectator to an actor, so we would feel a strong loss if Chile were to drop out," says Hernan Quintana, head of the astronomy department at Católica University in Santiago.

At the same time, they worry that the price tag, which includes annual operating expenses of $700,000 in addition to $9.2 million in construction costs, could squeeze funding for training, technology, and infrastructure—all of which would be needed to take full advantage of the telescope. "Chile now spends only $1 million a year on all of astronomy, and we are fighting every day to operate our department," says astronomer José Maza of the University of Chile. "So $700,000 is a lot of money to pay for the privilege of being a partner."

While the other partners have held up their end, the Chilean share—including $1.1 million a year for 1995 to 1997—is being held hostage until legislators work out the terms of a new law governing all future scientific facilities on Chilean soil. The rules for existing telescopes operated in Chile by NOAO, the European Southern Observatory (ESO), and the Carnegie Institution were hammered out privately by military governments in decades past, and the agreements were managed by the University of Chile. Although Chilean astronomers were awarded free viewing time on the U.S. telescopes and the projects' employees received diplomatic immunity—a valuable perk for importing cars duty free, for example—the Chilean government was not a partner.

The current government feels its planned investment makes the facility a national asset, but defining its status has proven contentious. In May the lower house passed a bill that would remove diplomatic status for Gemini's employees. That move was the last straw for the project's board of directors, already angry that the legislative snafu had frozen Chile's payments since 1995. So they voted to ask the National Science Foundation, the official U.S. representative in the project, to begin negotiations with the Australian Research Council (ARC), the country's major funding body for universities.

Australia has jumped at the chance. "Astronomy is one of our flagship research fields," says ARC Chair Max Brennan. "If we can't afford the [comparatively modest] cost of joining Gemini, then we ought to pack up our gear and switch to tiddlywinks." U.S. and Australian sources say that official acceptance from the education ministry could come as soon as midmonth.

But Gemini officials have given Chile until 1 September to meet its payment schedule and pass legislation that keeps the project's status on a par with ESO in all respects. If it does, Chile would be restored to full partnership and Gemini would bid g'day to Australia. If not, Chile would retain only limited privileges under the category of host country, including rights to 10% of the viewing time on the southern telescope.

A bill pending in the upper house would satisfy Gemini officials, but it must then be reconciled with the earlier bill. Chilean sources say such swift action is doubtful. "If AURA hadn't demanded changes, a law would have already been passed," says Oscar Rivera, Gemini project manager for CONICYT, Chile's national research agency. "But now it's very unlikely."

As the fight over partnership continues, Gemini officials face a more immediate, but temporary, obstacle to construction. A 1.5-meter snowfall atop Cerro Pachon, the Gemini site in northern Chile, has blocked dirt access roads and delayed work for 6 weeks as crews repair the damage. For project manager Mountain, however, it may offer a way to stay cool as the politics heats up.

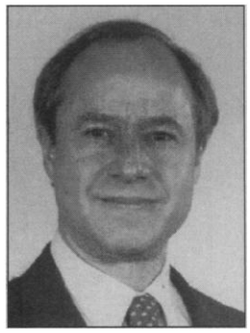
–Jeffrey Mervis

With reporting by Elizabeth Finkel in Melbourne.

BIOTECHNOLOGY

NIH Nixes Appeal to Bypass Patent Law

National Institutes of Health (NIH) director Harold Varmus sided with Johns Hopkins University last week in a high-profile patent dispute with a feisty biotech company, CellPro Inc. of Bothell, Washington. But Varmus also poured cold water on the claims of both sides: Some anticipated medical benefits of a widely touted cell-sorting technique at the center of the dispute have not been proved, he said.



Upheld. Hopkins patent holder Curt Civin.

Varmus's decision was the second major blow to CellPro in just over a week. On 24 July, Judge Roderick McKelvie of the federal court in Wilmington, Delaware, ordered the company to pay Hopkins and its commercial partners triple damages, amounting to $6,961,479, for infringing the university's patents. The penalty stemmed from a ruling McKelvie issued in March that Hopkins and its partners had exclusive rights to market a device that uses CD34 antibodies to separate stem cells from human blood or bone marrow. The cells are then infused to rebuild the immune system after the patients undergo toxic cancer therapy.

CellPro was the first company to develop a CD34 machine, and so far is the only company approved by the Food and Drug Administration (FDA) to market one. But Judge McKelvie ruled in March that CellPro was guilty of "misconduct" because it knowingly violated Hopkins's patents and the rights of Hopkins's partners, including Baxter Healthcare Corp. of Deerfield, Illinois, which has developed its own CD34 device. In addition to awarding damages to the Hopkins group last month, McKelvie told CellPro it must stop selling CD34 machines. CellPro issued a statement last week saying that it was "disappointed" with NIH's ruling, and its chief executive officer, Richard Murdock, announced that his company will appeal McKelvie's ruling.

Varmus was dragged into this dispute because CellPro had sought to bypass McKelvie's March ruling by appealing to NIH for an unusual waiver from U.S. patent laws that would have allowed it to continue marketing its CD34 device. Twelve U.S. senators and 25 representatives wrote letters to Donna Shalala, secretary of Health and Human Services, Varmus's boss, on CellPro's behalf. And Murdock—who himself was treated for a rare cancer with CellPro's device—appeared in magazines, newspapers, and on television this spring touting his apparent cure (*Science*, 6 June, p. 1490).

CellPro, noting that Baxter had been slower than CellPro to put a CD34 device on the market, claimed that "thousands of victims of the most acute forms of metastatic breast cancer ... would be forced to undergo less optimal treatment with unnecessary suffering, and, in some cases, death" if the judge's order was enforced. It also warned that clinical trials would be cut short, increasing the likelihood that children with leukemia undergoing cell transplant therapy would die.

NIH was not swayed, however. In a formal memorandum, Varmus says he has decided not to exercise "march-in rights" under the Bayh-Dole Act of 1980, which allows the government to take control of a federally funded invention if it is not being developed fast enough. In particular, he said he wasn't persuaded that cell-separation machines make a big difference to the health of cancer patients. There is "considerable debate" among experts as to whether these machines offer

any "clinically significant benefit to patients over standard hematopoietic transplantation techniques," the memo says. It also notes that FDA approved CellPro's device for a narrow use—reducing the toxic side effects of bone marrow transplants.

"To date," the NIH memo continues, "neither party has presented ... any studies documenting that cell separation devices improve stem cell engraftment, disease-free survival, or overall survival." It is "premature," NIH says, "for either Baxter or CellPro to claim patient benefits (other than a decrease in infusional toxicities)."

In reality, clinicians say, the CellPro machine is rarely used for bone marrow transplants; it is used mainly to separate stem cells from peripheral blood, an "off-label" use. Baxter has asked FDA to approve its own CD34 machine for use on peripheral blood. FDA has not acted as yet, and until it does, Baxter's machine may be used only in experimental studies.

Saying that it wants to involve itself as little as possible in the commercial battle, NIH deferred to Judge McKelvie on most points. In his 24 July opinion, McKelvie castigated CellPro for its "contempt" for Hopkins and Curt Civin—the Hopkins scientist who discovered and patented the CD34 cell-selection technique. He also ordered CellPro to turn over to Hopkins and its partners 60% of "incremental profits" on sales of its CD34 machines while it awaits a decision on its appeal. McKelvie also enjoined all U.S. sales of the CellPro machine, but held the injunction in abeyance until 3 months after Baxter wins approval from the FDA to market its device. Meanwhile, both McKelvie and Varmus have stated that they will monitor the need for CellPro's machine, and if they see evidence that patients who need this technology are not getting access to it, they will reconsider.

The hot potato now passes to FDA. On 24 July, an FDA advisory panel discussed Baxter's CD34 device and found it safe, but, according to the panel's chair, reached "no consensus" on efficacy. FDA has set no deadline for acting on the case.

–Eliot Marshall

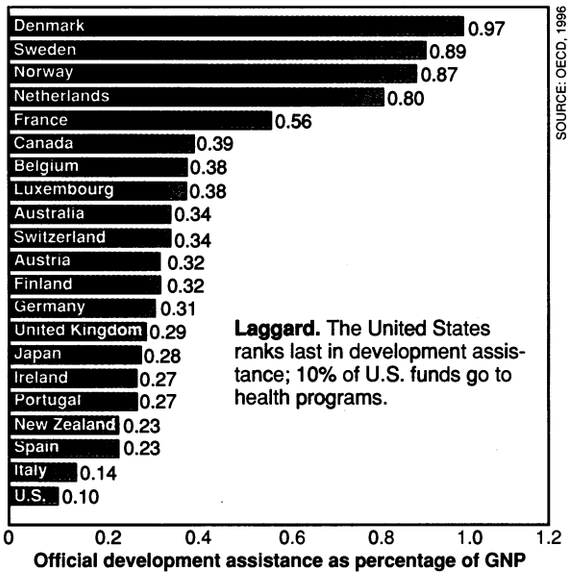
INFECTIOUS DISEASES

Congress Readies Injection of Funds

At a Senate hearing last May on the global spread of infectious diseases, Senator Patrick Leahy (D–VT) chided the U.S. government for treating "one of the most serious threats we face with the same kind of naïve optimism we did 20 years ago." Leahy, who persuaded the Appropriations Committee's Subcommittee on Foreign Operations to hold the hearing, included his colleagues in the blame: "Frankly, I am amazed that this topic has not received greater attention in the Congress." Those urgings have had an effect. Last month, the Senate passed an appropriations bill that earmarks $30 million in the budget of the U.S. Agency for International Development (USAID) to combat infectious diseases. And last week, a House committee held a hearing on a bill that calls for the USAID to spend $50 million "for targeted global programs to end infectious diseases."

Although USAID officials dislike Congress earmarking part of their budget in this way, they agree about the need to increase funding for emerging and reemerging infectious diseases such as malaria, tuberculosis, dengue, Ebola, and other plagues of poorer countries. Several prominent researchers are egging Congress on. "Let's face it, it's a real drop in the bucket, but it's a big drop," says Johns Hopkins University's D. A. Henderson, an epidemiologist whose past jobs have included leading the smallpox eradication program at the World Health Organization (WHO) and a stint at the White House's Office of Science and Technology Policy.

TB researcher Barry Bloom of New York City's Albert Einstein College of Medicine says current U.S. efforts against infectious diseases are disjointed. "The power of medical science to make a difference, were it to address the problems of people in the poorest countries, is quite remarkable, and yet there is no leadership that is linking biomedical science to global equity in health or foreign policy." For evidence of the paltry U.S. spending on these efforts, Bloom points to a report he co-authored for the Institute of Medicine earlier this year.* The report refers to 1996 data that ranked the United States dead last among industrialized countries in the proportion of the gross national product it spends on foreign aid (see graph), and it notes that only 10% of the total goes toward health assistance.



Laggard. The United States ranks last in development assistance; 10% of U.S. funds go to health programs.

A committee report accompanying the Senate bill says USAID should pass the money on to the WHO's Tropical Disease Research Program and its newly formed Division of Emerging and Other Communicable Diseases Surveillance and Control. The report also calls for giving some of the money to the Field Epidemiology Training Program of the U.S. Centers for Disease Control and Prevention (CDC). Henderson says the increase for disease surveillance is critical. "We're really investing very little money at the present time in anything that could be called surveillance," says Henderson. The CDC's Janis Videtto, who helps manage the $1 million budget spent on training epidemiologists at 17 sites around the world, says additional money is "sorely needed."

Sally Shelton-Colby, USAID's assistant administrator for global programs, expressed misgivings about the legislation when she spoke at the House hearing last week, however. Although she agreed that the international community is not doing enough in this area, she noted that her agency spent $320 million last year on infectious diseases, supporting such "fundamental prevention and control efforts" as family planning and economic development. Shelton-Colby said USAID could use new money to better monitor and fight TB, malaria, and the spread of drug-resistant pathogens, but she urged Congress to "resist the temptation to earmark funds," because it may force USAID to divert money from other equally important programs. "The committee should not be in a hurry to rob Peter to pay Paul," she said.

The fate of the House bill will be decided when Congress returns from its recess in the beginning of September. Then the House and the Senate will meet in conference to decide exactly how much money—if any—to devote to the effort.

–Jon Cohen

* "America's Vital Interest in Global Health," Institute of Medicine, Board on International Health, is available on the Internet at http://www.nap.edu/readingroom/books/avi