Biomedical briefing

DRUGS

Patent payout

Several recent outcomes in US Federal court mean that Gilead Sciences must pay for its infringement of two Merck patents that protect compounds that inhibit viral replication in diseases such as hepatitis C. The legal wrangling began in 2013, when Merck notified Gilead that it had reason to believe that two of the latter's hepatitis C drugs, Sovaldi and Harvoni, contained compounds developed using the former's patented research. In response, Gilead filed suit against Merck and partner Ionis Pharmaceuticals in 2013 to declare the patents invalid. However, Merck countersued Gilead for patent infringement. In February 2016, a judge ruled on the countersuit, finding that Gilead had infringed on the patents. On **22 March**, a jury reached a verdict on Gilead's 2013 lawsuit, declaring Merck's patents valid. Two days later, the same California jury awarded Merck $200 million in damages for its 2013 lawsuit to be paid by Gilead Sciences, although, as *Nature Medicine* went to press, a non-jury trial was planned to decide if, going forward, Merck would also be awarded 10% royalty on Gilead's sale of its two drugs. Michele Rest, a spokesperson for Gilead, told *Nature Medicine* that the company plans to appeal the damages ruling.

Therapeutic first

The European Medicines Agency's (EMA's) Committee for Medicinal Products for Human Use (CHMP) recommended Strimvelis (GSK2696273) for approval on **1 April**. If approved by the EMA, Strimvelis would become the world's first gene therapy intended specifically for children. Made by GlaxoSmithKline, Strimvelis is used to treat children who have an immune disorder known as adenosine deaminase deficiency–severe combined immunodeficiency (ADA–SCID). The rare genetic disease results in a total lack of mature lymphocytes, which are essential for staving off infection. Children with the condition rarely live past the age of two. In the therapy, patients' bone marrow cells are extracted, engineered to carry a working copy of the gene that is mutated in ADA–SCID and then re-introduced into the patient to facilitate the production of lymphocytes.

Kristoffer Tripplaar/Alamy Stock Photo

Theranos trouble

A 147-page document made public on **31 March** by the US Centers for Medicare and Medicaid Services (CMS) provided details about deficiencies in the safety and accuracy of blood testing conducted by the consumer health-technology company Theranos. It also included details about the company's plans to address those deficiencies. Theranos has developed tests that cost fivefold less on average to collect than blood tests from other diagnostic companies, and that use only a few drops of blood, rather than a vial. During an inspection in November of Theranos's lab in Newark, California, the CMS, a federal agency that regulates clinical laboratory testing, found problems with Theranos's analytic systems, quality-control procedures and personnel qualifications. One blood-clotting test was found to be so flawed that it could "pose immediate jeopardy to patient health and safety," according to a letter sent to Theranos by the CMS in January. Since learning of the CMS's findings through this letter, the company has announced enhanced quality-control measures in its laboratories and the suspension of any flawed testing, as well as the addition of members to its scientific and medical advisory board. As *Nature Medicine* went to press, it was revealed that Theranos is under investigation by both the US Securities and Exchange Commission and the Department of Justice.

Scrapped merger

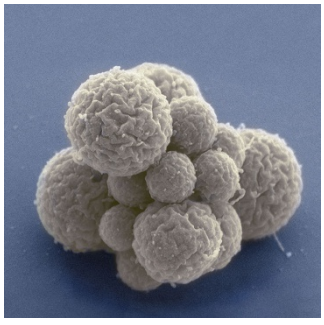
On **6 April**, pharmaceutical companies Pfizer and Allergan called off a proposed merger that would have created the world's largest pharmaceutical company. The announcement followed new rules introduced two days earlier by the US Department of Treasury, which the companies qualified as an "adverse tax law change" that motivated them to terminate the proposed merger. Analysts point out that whereas US-based companies have merged with foreign-based companies to take advantage of lower tax rates outside the US in the past, the new rules reduce the incentives for such a move. For instance, the regulations

place restrictions on the money that a foreign counterpart can lend its US subsidiary to enable it to reduce the amount of taxes that it owes the US government. Pfizer agreed to pay Allergan $150 million for expenses associated with the merger thus far.

RESEARCH

Synthetic life

Scientists with Synthetic Genomics, a California-based company that develops genetically modified microorganisms to produce biofuels and chemicals, and with the J. Craig Venter Institute (JCVI) reported on **25 March** that they had created a synthetic bacterial cell containing the least number of genes of any known cellular organism (*Science*, doi:10.1126/science.aad6253, 2016). The bacterium, called JCVI-syn3.0, is the third synthetic organism that the team has produced, and its unique genome contains only 473 genes—52 fewer than in the bacterium *Mycoplasma genitalium*, which held the previous record. By systematically removing genes from the first of its synthetic organisms, the company arrived at JCVI-syn3.0's genome, which contains the minimal amount of genetic information needed for it to live and grow under laboratory conditions. "The generation of a minimal cell is a major step toward understanding how cells work at the most fundamental level," Daniel Gibson, an author on the study, told *Nature Medicine*.



Thomas Deerinck and Mark Ellisman, NCMIR

BMI booms

Measurements of body mass index from more than 19 million individuals from 186 countries reveal a rapid worldwide rise in obesity, according to research published on **2 April** (*Lancet* **387**, 1377–1396, 2016). Between 1975 and 2014, the percentage of women who are obese rose from 6.4% to 14.9%, and the percentage of men rose from 3.2% to 10.8%. And whereas undernourishment has decreased globally over the same time period, falling from 14.6% to 9.7% in women and 13.8% to 8.8% in men, in a few countries, as many as one in five people are underweight. "We shouldn't let the global dialogue on growing obesity overshadow the fact that there are some communities that still need sufficient nutritious food," says Majid Ezzati, a researcher at Imperial College London and an author on the study. Both obesity and undernourishment can be fought with policies that increase the accessibility and affordability of healthy foods, according to Ezzati.

Thwarted editing

Researchers reported on **7 April** that an attempt to edit the HIV virus out of the genomes of host cells resulted in a virus that developed mutations in response to the editing and became resistant to future attempts at gene editing (*Cell Reports*, doi:10.1016/j.celrep.2016.03.042, 2016). In the study, researchers used clustered regularly interspaced short palindromic repeats (CRISPR)–Cas9 technology to try to create mutations in HIV genomes in white blood cells that would inactivate the virus. Although the researchers observed this outcome in some scenarios, in other scenarios, DNA sequencing revealed that CRISPR–Cas9-based editing of HIV genomes resulted in an insertion of mutations that did not inactivate the virus but that did prevent further editing by CRISPR–Cas9. The authors of the study, based at McGill University in Montreal, suggest that it may be necessary to target multiple mutations through gene-editing techniques to inactivate HIV successfully.

PEOPLE

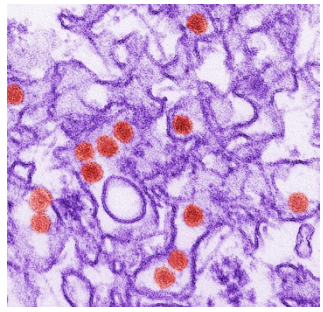
Sanofi R&D

The French pharmaceutical giant Sanofi appointed immunologist Yong-Jun Liu as its new head of research for global research and development (R&D), starting on **1 April**. Liu had served as head of research at MedImmune, a subsidiary of British pharmaceutical company AstraZeneca, since January 2014. Liu has spent more than 25 years researching and identifying drug targets for the treatment of allergies, cancer and infection, and in 1997, he led a team that notably discovered plasmacytoid dendritic cell precursors, which ultimately help to support the body's response to viral attacks. Liu will report to Elias Zerhouni, Sanofi's president of global research and development. Zerhouni told *Nature Medicine* that Liu's multicultural exposure working in China, Europe and the US makes him "perfect for a large, international research company like ours," and that Liu will lead Sanofi toward a focus on immunology and translational medicine.

POLICY

Funding transfer

US President Barack Obama's administration announced on **6 April** that it would dedicate $589 million from pre-existing emergency funds to fight the ongoing Zika virus outbreak. In February this year, the administration requested more than $1.8 billion in funding from US Congress to fight the virus, but Congress has yet to make a decision on the request. Of the $589 million being re-directed, $510 million will come from the emergency fund that the US set up to fight Ebola during the outbreak in 2014, and another $79 million will come from other public-health-emergency funds. In a blogpost on the White House website, Shaun Donovan, director of the US Office of Management and Budget, wrote, "We continue to call on Congress to take immediate action to provide the full requested amount for the emergency supplemental, but in the absence of Congressional action, we must scale up Zika preparedness and response activities now."



David Cole/Alamy Stock Photo

FUNDING

Immunotherapy investment

The Parker Foundation, a philanthropic organization set up by Napster co-founder and past Facebook president Sean Parker, announced on **13 April** the allocation of a $250-million grant to establish the Parker Institute for Cancer Immunotherapy. The newly established Institute will foster collaboration among 300 researchers from more than 40 labs in six cancer-research institutions across the US, including the Memorial Sloan Kettering Cancer Center in New York, the University of Pennsylvania in Philadelphia and the MD Anderson Cancer Center in Houston. The initiative has identified three main goals in the field of immunotherapy: to develop more effective T cell therapies, to broaden the use of checkpoint-blockade therapeutics and to continue research on anticancer vaccines.