NEWS IN BRIEF

Supreme Court rules on DNA patents

Isolated DNA is not eligible for patenting, but synthetically created cDNA remains eligible.

The lowdown: A long-running case between genetic testing company Myriad Genetics and opponents of "gene patenting" has come to an end. The dispute focused on three patents owned by Myriad relating to two human genes, breast cancer type 1 susceptibility (*BRCA1*) and *BRCA2*, and protecting diagnostic tests that determine an individual's susceptibility to breast and ovarian cancer. Several plaintiffs, including the Association for Molecular Pathology, the American Civil Liberties Union and patient groups, alleged that these patents were invalid because they claim products of nature.

In the decision issued by the US's highest court last month, judges ruled that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated" (see go.nature.com/ggAGlq for the full decision). Although the plaintiffs argued that cDNA should not be eligible for patent protection either because the nucleotide sequence of cDNA is dictated by nature (that is, by the mRNA template), the Court upheld the viability of cDNA patents. Scientists "unquestionably create something new when cDNA is made … [that is] distinct from the DNA from which it was derived," wrote the judges.

Both sides asserted their victory. Myriad said it still has strong patent protection for its BRCA tests, whereas the Association for Molecular Pathology said the ruling was the "right decision for the future of medicine and science … and most importantly patients".

The decision departs from the long-standing practice of the US Patent and Trademark Office, which previously permitted the patenting of isolated DNA. It also puts the United States at odds with jurisdictions such as Europe and Australia, where isolated genes remain patent eligible. Because the number of patents granted with claims to a simple isolated DNA peaked in the late 1990s, and many of these patents are due to expire soon, the decision is unlikely to impact a large number of patents. Moreover, many diagnostic patents rely on method claims, which were not under scrutiny in the current case.

Two approvals boost melanoma arsenal

The US Food and Drug Administration approved GlaxoSmithKline's first-in-class trametinib and second-in-class dabrafenib for the treatment of patients with *BRAF*-positive advanced or unresectable melanoma.

The lowdown: The approval 2 years ago of Bristol-Myers Squibb's immunotherapy ipilimumab and Roche's kinase inhibitor vemurafenib for the treatment of metastatic melanoma marked a major shift in the melanoma treatment space (*Nature Rev. Drug Discov.* **10**, 325–326; 2011). Two new approvals in the United States offer further welcome options for metastatic melanoma patients with *BRAF* mutations, who make up approximately half of the patients with metastatic melanoma.

Trametinib is the first MEK (MAPK/ERK kinase) inhibitor to be approved. MEK — which lies downstream of BRAF — has a key role in the regulation of cell growth and is activated in many cancers, but bioavailability, pharmacokinetics and toxicity issues have long delayed the development of MEK inhibitors (*Nature Rev. Drug Discov.* **11**, 819–820; 2012). GlaxoSmithKline's agent overcame these issues, most notably increasing progression-free survival in a Phase III trial of patients with $BRAF^{V600E}$ or $BRAF^{V600K}$ mutations (*N. Engl. J. Med.* **367**, 107–114; 2012).

Dabrafenib is the second BRAF inhibitor to be approved, trailing Roche's vemurafenib. It is approved for the treatment of patients with $BRAF^{V600E}$-positive metastatic melanoma.

Both agents were approved with companion diagnostics for the detection of the relevant *BRAF* mutations. GlaxoSmithKline is now testing the two agents together in combination. A wave of experimental immunotherapy agents are also attracting attention in part because of their efficacy in melanoma (see page 489).

FDA asks for input on antibiotic drug development

A US Food and Drug Administration (FDA) taskforce working on advancing antibiotic drug development has outlined its initial areas of interest, and the FDA has proposed a list of pathogens that could trigger extended exclusivity periods for drug candidates.

The lowdown: Last September the FDA announced the formation of an Antibacterial Drug Development Task Force "to identify priority areas and to develop and implement possible solutions to the challenges of antibacterial drug development". The Task Force has now put out a call for public input into study design issues (including the use of Bayesian and adaptive approaches as well as surrogate and clinical end points that can be measured earlier than irreversible morbidity and mortality) and for the development of guidance for specific bacterial indications (including complicated urinary tract infection, uncomplicated gonorrhoea and complicated intra-abdominal infection). Input is due by 30 July (see go.nature.com/RWRoj2 for details).

The FDA also moved forward with the Generating Antibiotic Incentives Now (GAIN) initiative, a provision in last year's Food and Drug Administration Safety Innovation Act that seeks to encourage the development of new antibacterial and antifungal drugs. GAIN provides 5 additional years of exclusivity to agents that are classified as qualified infectious disease products (QIDPs). Following consultation with infectious disease and antibiotic resistance experts, the FDA has now issued a proposed list of the "qualifying pathogens" that can be used in the designation of the QIDPs. The list consists of: *Acinetobacter* species, *Aspergillus* species, *Burkholderia cepacia* complex, *Campylobacter* species, *Candida* species, *Clostridium difficile*, *Enterobacteriaceae*, *Enterococcus* species, *Mycobacterium tuberculosis* complex, *Neisseria gonorrhoeae*, *Neisseria meningitidis*, Non-tuberculous mycobacterial species, *Pseudomonas* species, *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus pneumoniae*, *Streptococcus pyogenes* and *Vibrio cholerae*. Input is due by 12 August (see go.nature.com/9CZc71 for details).