Next Generation Therapeutics and Technologies

IP *challenges* in Personalized Medicine Drug Development

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Personalised medicine: The future of healthcare, based on individual patient data

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Personalised medicine in Europe – is the patent system keeping up?

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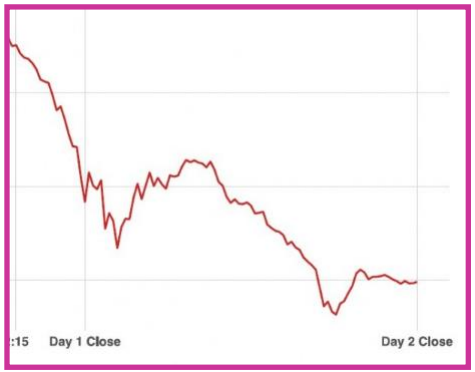
Personalized Medicine Gets Boost From Court Ruling on Patents



Personalized medicine industry in distress over Supreme Court's tightening of patent laws

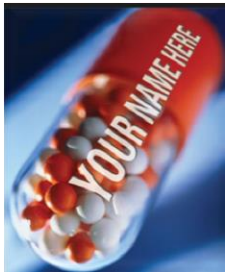
Heidi Ledford | August 19, 2016 | Nature

PRINTER FRIENDLY

Rejections for US patents related to personalized medicine have spiked after recent Supreme Court decisions tightened the rules

Personalized Medicine…

- Hailed as revolution in human health[1]
  - 150+ FDA-approved drugs with pharmacogenomic information in labeling[2]
  - Nearly 50% of Phase1 pharma pipeline have associated diagnostics[3]



and also

- A challenge to the patent system
- IP is imperative for successful development and exploitation
  - Thought-out IP strategy

1: Nature 464:674 (2010)
2: FDA Table of Pharmacogenomics Biomarkers in Drug Labelling
3: McKinsey Report "PM: the path forward, 2013"

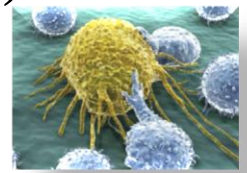
…comes in many shapes and forms…

- Better definition of disease and/or prognosis
  (Philadelphia chromosome/chronic myeloid leukemia; led to imatinib).

- Excluding patients at risk experiencing serious adverse events
  (e.g., HLA B 5701 and abacavir in HIV).*

- Predicting drug responses
  (trastuzumab in breast cancer with Her-2 overexpression).

- Screening for drugs, dose-adjustment, individualized (combination) therapy, sequential therapy.



…each with its own IP strategy.

Personalized IP strategy drivers include

- Business objectives
- Type of invention
- Patentability and infringement
- Need to collaborate with third parties

Strategy

Business objectives: Initial patent filing

Early development stage inventions

Commercial value?
Lead to e.g. operative companion diagnostic?

Competitors: Freedom-to-operate-risk
(use of biomarker in clinical trials)

Broad & speculative claims may preclude subsequent patents
(of you or collaborating third party; with later expiration dates!)

Sufficient (experimental) support re: claims

Type of invention: New group of patients (EPO)

Compound X in treating disease Y …

- in patient with biomarker A.
  (epi Information 2012: a patient with the [biomarker] will have inevitably been treated*)*[1]

- comprising assaying sample from patient, determining if patient has biomarker A, and administering X if biomarker is present[2].

Needs evidence link between presence or absence of biomarker and improvement in the treatment.

No/incomplete evidence may preclude patentability

1: Despite G5/83, T1399/04 & T836/01
2: Eli Lilly and Company AIPLA 2012

Patentability: Moving target

Patentability

-Visit our yearly workshop-

<u>Jurisdictions</u>

USA (Mayo, Myriad and Alice): biomarkers, DNA, methods comparing

CA: diagnostics based on correlation

AU: DNA claims

EPO: Methods of treatment

<u>Raising the bar</u>

Marker selected from group (data only on group): X

Antibody against target (no specifics): X

Infringement:

-150+ FDA-approved drugs with pharmacogenomic labeling
-FDA-approved tests

Vemurafenib: metastatic BRAFV600E as detected by an FDA-approved test.
Test: cobas® 4800 BRAF V600 Mutation test.

Method of treating …comprising testing for BRAF & administering vemurafenib if tested positive [with cobas®]

Method of identifying patients eligible for treatment with Vemurafenib comprising testing for BRAF [with cobas®]

To conclude

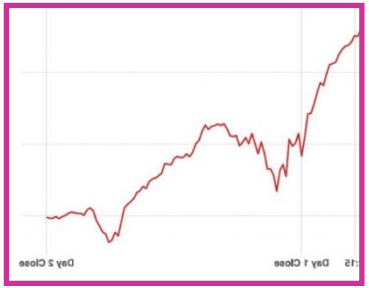
Imperative for personalized medicine

to have

personalized IP strategy and lifecycle management

during and for

development and commercialization



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