WINNING STRATEGIES:
How to Create, Grow, and Sustain a Successful Life Sciences Company

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PMC Personalized Medicine Coalition

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WINNING STRATEGIES: How to Create, Grow, and Sustain a Successful Life Sciences Company

New Paradigms for Advancing Personalized Medicine

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Panelists

Moderated by:

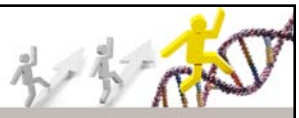
Antoinette Konski, Partner, *Foley & Lardner LLP*

Speakers:

Anita Chawla, Ph.D., Vice President, *Analysis Group*

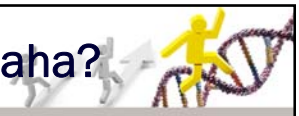
Ken Goldman, Global Head, Diagnostics Patents, *Novartis Vaccines & Diagnostics, Inc.*

Suneel Ratan, Founder and CEO, *Care Architecture*



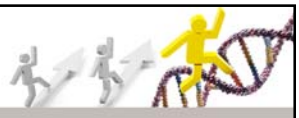
Ken Goldman, Global Head, Diagnostics Patents, *Novartis Vaccines & Diagnostics, Inc.*

Prometheus – What's the Brouhaha?



- Patentable Subject Matter
  - Any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof
- Unpatentable Subject Matter
  - Laws of nature
  - Natural physical phenomena
  - Abstract ideas / Purely mental processes

The *Bilski* Saga

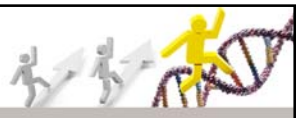


- The old "machine or transformation" test
  - A process is patentable if:
    - It is tied to a particular machine or apparatus, or
    - It transforms a particular article into a different state or thing.
- The new test after *Bilski*
  - "machine or transformation" test is a "useful and important clue", but is not the sole test
  - The Supreme Court agreed with *amici* that to hold otherwise would create uncertainty for, *inter alia*, advanced diagnostic medicine techniques

Prometheus-type claims

- General claim structure
  - 1. Testing a patient or patient sample.
  - 2. Choosing a treatment based on test outcome.
- Specific claims in *Prometheus*
  - Administering a thiopurine to a patient suffering from an autoimmune disease
  - Measuring the level of thiopurine metabolite in patient
  - Potentially warning physician to adjust dosage if metabolite is outside of certain range.

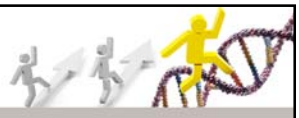
Outstanding issues



- Who infringes the claim?
  - The testing lab
  - The physician
  - Both as “contributory” infringers
- What is the *real* issue?
  - Patentable subject matter
  - Effect of discovering “correlation”
  - Physical steps after correlating?

Scope of *Prometheus* effect

- Pure diagnostics
- Companion diagnostics
- Prognostics (determining patient susceptability to future disease)
- Choosing among various therapies
- Therapy optimization
- Warnings

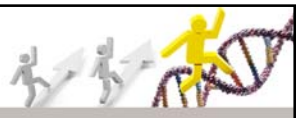


Suneel Ratan, Founder and CEO, *Care Architecture*

What's The Question?

- How do we provide an information wrapper for traditional therapies?
- How do we monitor for issues such as medication conflicts?
- How do we support the whole person?

HIT as Personalized Medicine?

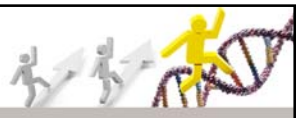


- Increasingly personalized support for behavior and monitoring
- Medical vs. non-medical risk factors
- Cost-reduction tool vs. therapeutic adjunct

Where is this Headed?

- Large data sets
- Dynamic assessment of and personalized support for risk factors - what's going on with you today?
- Dynamic titration and adjustment
- Impact on research - genotype vs. phenotype

Things to Ponder



- This changes everything
- Inevitable, but …
- How do we get this flywheel going?

Anita Chawla, Ph.D., Managing Principal, *Analysis Group*

Challenges in development and commercialization of PM

- Promise of personalized medicine (PM) presents real opportunities for better clinical management
- Gold standards exist for evidence generation
  - Clinical validity, clinical utility, and value
- Regulatory pathway has been updated, but guidance is relatively general versus specific
- For new PM tools, such as diagnostics, payer evaluations and associated decisions are not yet systematic or predictable

Lack of clarity creates a dilemma for manufacturers—particularly in the context of coverage and reimbursement decisions

Coverage decisions are consistent across plans but vary across Dx

Test Target	Associated Treatment(s)	Economic Studies (2000-2010)	Price ($)	Medical Coverage Decisions		
				Aetna	Cigna	Humana
ACE genotyping	Statins	2	€49	N	N	N
BRCA1/2	Prophylactic surgery	6	300-3,000	Y	Y	Y
CYP2C19	PPIs / Clopidogrel	2	600-1300	N	N	N
CYP2C9 / VKORC1	Warfarin	8	199-550	N	N	N
CYP2D6	SSRIs	1	600-1300	N	N	Y
EGFR	EGFR tyrosine kinase inhibitors	1	97	N/A	N/A	Y
Hepatitis C genotyping	Pegylated interferon	2	75	Y	Y	Y
HER2	Trastuzumab	2	43-145/ $600+	Y	Y	Y
HLA -B*5701	Abacavir	2	68	Y	N/A	Y
KRAS	Cetuximab / Panitumumab	1**	452	Y	Y	Y
Lynch syndrome (HNPCC)	Surgery	8	261-457	Y	Y	Y
MCADD	Diet, L-carnitine	2	5-50	Y	Y	Y
MTHFR	Methotrexate	1	50	N	N/A	N
Oncotype Dx	Adjuvant chemo for breast cancer	2	3,975	Y	Y	Y
TPMT	Thiopurines	9	395	Y	Y	Y
UGT1A1	Irinotecan	2	375	N	N	N

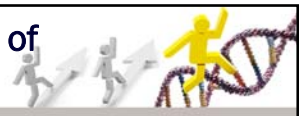
** - Included study is an abstract.
Note: An additional 41 economic studies were identified for other, unclassified genetic tests

Sources: (1) Vegter S, Boersma C, Rozenbaum M, et al. Pharmacoecnomic evaluations of pharmacogenetic and genomic screening programmes – a systematic review of content and adherence to guidelines. Pharmacoeconomics 2008;26(7):569-587. (2) Meckley LM, Neumann PJ. Personalized medicine: factors influencing reimbursement. Health Policy 2010;94:91-100. (3) AG research

Reimbursement context may not appropriately reward value

- Are the incentives in applying and reimbursing novel approaches aligned?
  - Continuous care versus episodic care
  - Will cost savings be generated, which is typically an expectation for PM
- Fee schedules have not kept pace with innovation
  - Molecular versus conventional diagnostics

PM demands the right evidence, or value of personalization cannot be captured



- Prospective evidence is key
  - Best way to prove clinical utility and value BUT
  - Extra time and resource in a clinical program
  - Potential delay in regulatory filing
  - Potentially greater risk in clinical strategy, but lower risk in reimbursement
- Building the case on retrospective evidence is much harder
  - Adequate proof of impact on patient outcomes challenging

A set of data that is sufficient for regulatory approval may not be sufficient for favorable reimbursement; data on economic impact will be increasingly required

Assessing the TPP, likely evidence, and stakeholder expectations may reveal need to update clinical programs

Dimension	Evidence
Product description	▪ Anticipated label information including indication, dosage, administration, etc.
Target population & place of product in therapy	▪ Disease definition, genetics, epidemiology ▪ Prognostic and diagnostic tests ▪ Subpopulations defined by biomarkers ▪ Burden of disease ▪ Current treatment options
Clinical and economic outcomes	▪ Systematic review and summary of published clinical and economic studies ▪ Meta-analyses and HTA
Value assessment	▪ Cost of diagnosis, treatment, monitoring, and adverse event management versus patient outcomes such as survival, events avoided, symptoms managed or alleviated, etc.
System impact	▪ Health plan budget impact ▪ Expected penetration rate (market share)

Strengths	Weaknesses
▪ Product characteristics (e.g., MOA, mode of administration) ▪ Product claims based on evidence (safety, efficacy)	▪ Serious adverse events or safety signals ▪ Inability to claim key attribute relevant for TA
Opportunities	**Threats**
▪ External environment trends & market forces ▪ Stakeholder need that may be addressed by product ▪ Opportunities to improve positioning	▪ CER systematic review ▪ New competitive entrant –targeted, specific MOA ▪ Risk/harm/impact of potential weakened position

Thank You!

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