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DIRECTORATE FOR SCIENCE, TECHNOLOGY AND INDUSTRY
COMMITTEE FOR SCIENTIFIC AND TECHNOLOGICAL POLICY

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Working Party on Biotechnology

KNOWLEDGE MARKETS IN THE LIFE SCIENCES

Outcomes of the Expert Workshop and Future Work

24th Session of the WPB
19-21 November 2008

This document reports on the Expert Workshop on Knowledge Markets in the Life Sciences held 16-17 October 2008 in Washington DC. It identifies workshop outcomes and suggests possible follow on themes for the WPB in 2009-2010.

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SECRETARIAT NOTE

This document presents the outcomes of the recent Expert's Workshop on Knowledge Markets in the Life Sciences which was held on 16-17 October 2008 at the US National Academies of Science in Washington, DC. The Agenda of the Workshop is in Annex 1; the draft Chairs' Summary of the discussion points is in Annex 4.

This document presents the plans for developing a Policy Report based on the Rapporteur's report of the workshop, the speakers' presentations, the Chairs' Summary of the discussions, and on the other background papers prepared for the workshop. The WPB will be asked to comment on the draft Policy Report and with a view to declassification in early 2009. The WPB is asked to discuss at its November 2008 its preference regarding the process for declassification.

In addition, this document suggests avenues for further work related to Knowledge Markets in the Life Sciences which are based on the suggestions made at the Workshop. It presents several possible areas of future activity. These might be taken forward in 2009-2010 under output result 3 [Reports on Infrastructures for the Life Sciences] of the WPB PWB. WPB delegates are asked to discuss which avenues of work they are most interested in pursuing and how they would like to proceed to develop these.

Action points:

- **Discuss** the draft Chairman's Summary [Annex 3].
- **Comment** on the proposed Policy Report structure.
- **Agree** process for the declassification of the Policy Report.
- **Discuss** options for future work.
- **Agree** a process for developing new projects related to Knowledge Markets.

KNOWLEDGE MARKETS IN THE LIFE SCIENCES

1. This paper reviews the objectives, discussions and conclusions of the workshop on Knowledge Markets in the Life Sciences. In addition, it proposes the development of a Policy Report and identifies follow on work options for discussion by the Working Party on Biotechnology at its 24th Session in November 2008.

Background

2. In the biomedical sector, new mechanisms are emerging to facilitate the exchange and trade of a variety of intellectual assets (*e.g.* data, materials, expertise, knowhow, services) important in the advancement of science. Such "knowledge markets" encourage knowledge sharing and creation; they may also increase the speed and efficiency with which health-related research is translated into innovative goods and services as well as the returns on investments made.

3. The Working Party on Biotechnology held an expert's workshop on "Knowledge Markets in the Life Sciences" in Washington, DC on 16-17 October 2008. The workshop brought together experts from academia and public research organisations, health and IT industries, the investment community, non-governmental organisations, as well as policy makers. The purpose of the Workshop was to explore the present structures and uses of Knowledge Markets, how they impact innovation, whether they could be more broadly used and what governments can do to help make knowledge markets become a reality while delivering on societal expectations.

4. Specifically, the workshop explored: *i)* what "Knowledge Markets" are by discussing their theoretical basis and real world examples of current exchange mechanisms; *ii)* what are the business, economic and policy incentives behind the creation of knowledge markets in the life sciences; *iii)* what types of health data, information, and know-how could create greater added-value if more easily exchanged or traded; *iv)* what impacts knowledge markets might have on biomedical innovation and health outcomes; *v)* new business models and opportunities that open up due to the use of knowledge markets; and *vi)* the factors that influence their development and impact including government policies. [See Annex 1 for the Workshop Agenda which describes these topics in greater detail.]

Synopsis of workshop discussions

5. The objective of the meeting was to increase awareness among policymakers about new trends in organising access to data, knowledge, and information in the life sciences as well as the means developing for exchanging such information. The recently developed exchange mechanisms, which can be called "knowledge markets," potentially improve access to widely distributed knowledge and the efficiency of knowledge usage in the biomedical sciences. These mechanisms have emerged in the past few years in response to technological opportunities (*e.g.* digitisation of data and the Internet), to changing public policy priorities in health and research, but also in response to financial pressures and evolving pharmaceutical and biotechnology business practices. The workshop demonstrated that there is enormous scientific and commercial potential if one can encourage a more networked and evidence based biomedical research infrastructure. It identified some key areas – IP guidelines, knowledge market frameworks, technology neutral infrastructure development and sustainable financing, their promotion for health or industrial policy objectives, their measurement – where government policies will influence the emergence of knowledge markets.

6. Workshop participants were very excited at the technological opportunities opening up with the greater uptake of bio-informatics, electronic markets, and the ability to network multiple sources of data to flexibly accommodate different research and clinical uses. Biomedical research in the 21st Century is finally becoming a scientific, data-centric and evidence-based field. But the different elements of the biomedical research infrastructure – the knowledge, data, information, materials, inventions - are widely dispersed, so knowing about and accessing these requires a complex of permissions, licenses, collaborations. In the development of innovative products and processes, the private sector including large integrated pharmaceutical firms increasingly rely on outsourced knowledge and technologies.

7. The mechanisms which are used to reduce costs and risks of outsourced research knowledge can be called – and increasingly are recognised as -- markets for the exchange of knowledge intensive assets. The extent to which, the knowledge assets are explicit, discrete (as opposed to bundled) and individually valued, varies. But the general sense was that knowledge intensive assets are being traded in a variety of knowledge markets, and that the trend will continue such that virtual, networked innovation in the health sector will increasingly be the norm. This inevitably has implications for scientific and research policy, industry structure and business strategies, IP access and management and possibly public health policies.

Process and outcomes

8. The Expert Workshop took place under the Innovation and Health work stream of the 2007-2008 Programme of Work and Budget (1.3.3., Output Result 1). It is a follow-on project to the work on "Emerging Research Models for Health Innovation" which took place in 2005-2006.

9. At the November 2007 and February 2008 sessions of the WPB, delegates agreed to organise a workshop in 2008 on "Knowledge Markets" and how these can be used to improve the innovation process, particularly but not exclusively in the health sector. The WPB urged that comparisons be drawn between health and other sectors where possible. In February 2008 the United States volunteered to host the meeting at the US National Academies of Science and provided a core voluntary contribution. Japan and the Netherlands also provided voluntary contributions, and Canada provided in kind support by agreeing to provide a rapporteur for the Workshop.

10. A steering group was established which included: Australia, Canada, Italy, The Netherlands, United Kingdom, the United States and BIAC. The Steering Group worked electronically and met once in Paris in June 2008 to agree the Agenda of the Workshop and speakers, as well as to discuss the issues paper and identify background reading materials. [See Annex 2 for the Issues Paper prepared to explain the workshop background and objectives to participants; and Annex 3 for the Background Reading on what is driving changes in knowledge management in the health sciences and what role knowledge markets are likely to play in future business models and industrial organisation.] The steering group on Knowledge Markets met back to back with the Steering Group on Collaborative Mechanisms (as well as the 2nd Session of the Task Force on Biomedicine and Health Innovation) so as to ensure cross-fertilisation and coordination.

11. The Workshop outputs consist of *i)* a Chairman's Summary of the main messages identified at the Workshop which will be added to the website for the Workshop (www.oecd.org/biotechnology) along with speaker presentations, the Agenda and Issues Paper; and *ii)* a Policy Report which will be produced over the winter of 2008. The Chairman's summary is out for consultation with the session Chairmen, the Steering Group and Participants for comment. [See Annex 4 for a draft of the Chairman's Summary.] A final version should be posted on the OECD website by end of November 2008.

12. The Policy Report will be based on the rapporteur's report being prepared by an outside consultant, the speaker presentations, and the background materials for the meeting. It is expected the report will be between 30 and 50 pages long. It will explain what knowledge markets are, their use in the health and life sciences, their potential impact and spread, and some of the policy issues that they raise. It will be an important contribution to our understanding of the evolution of research infrastructures and industry organisation in health. The proposed structure for the Policy Report is in Box 1.

Box 1. Draft Structure for the Policy Report on Knowledge Markets

1. Executive Summary of the workshop messages
2. Introduction to Workshop objectives
3. Summary of expert discussions on each session topic, including:
   - Theory and definition
   - Policy interest
   - Examples of KM in Health and in the Life Sciences
   - Valuation of knowledge intensive intellectual assets
4. Thematic issues raised at the workshop
   - Are KMs becoming more numerous, why?
   - What are the incentives for participation: public and private sector?
   - What are the elements necessary for the establishment of KMs, what are the challenges?
   - Do KMs enable new research or business models?
   - What benefits accrue from KMs (*e.g.* scientific, knowledge management, regulatory change, public health) and how can these be documented or measured?
5. Conclusions: Policy opportunities and challenges

13. The goal is to send the draft Policy Report for comment to experts and to the WPB in February 2009. If there is general agreement then the report might be cleared through WPB for consideration by CSTP at their meeting in March. This would allow publication of the report in the first half of 2009.

Action points:

- **Discuss** the draft Chairman's Summary [in Annex 3].
- **Comment** on the proposed Policy Report structure [Box 1].
- **Agree** process for the declassification of the Policy Report.

Related work within the OECD

14. The OECD has broad expertise in a number of areas related to knowledge markets. Within the remit of the Working Party on Biotechnology the work on collaborative mechanisms for access to

intellectual property, new research models for health innovation, the Guidelines on Licensing of Genetic Inventions, and the work on research infrastructures including the Human Biobanks and Genetic Research Databases and BRCs share similar concerns about how to ensure access to knowledge, encourage collaboration, promote interoperability, network remote and disparate research resources, and encourage efficient translation of research into new products and services.

15. Other committees in the OECD are also interested in knowledge flows, knowledge management, intellectual asset identification, measurement, valuation and exchange. Summaries of some of the relevant OECD documents can be found in Annex 3. Their recent focus has been on the following issues:

- **DSTI/EAS.** The NESTI Working Party has a long-standing interest in measuring the stock and flow of intellectual assets within firms and across firms (primarily through the collection of statistics on patents and licenses and the development of new indicators). It has recently completed a survey of patent licensing [DSTI/EAS/STP/NESTI(2008)21] which aims to better understand business strategies in licensing.

- **DSTI/STP**. The Working Party on Technology and Innovation Policy completed a project in 2006 on the *Valuation and Exploitation of Intellectual Property*, DSTI Working Paper 2006/5]. The report argues that firms are shifting to more open models of innovation, by which is meant more collaboration and external sourcing of knowledge. Efficient technology markets and effective IP valuation schemes become increasingly important, both for attracting capital and for trade. The report focuses on trends in firm exploitation of patents and new approaches to assessing patent values. It also identifies supportive government policies (patent administration, disclosure of patent and licenses, match making services, TTOs, SME training, reporting guidelines, financial incentives, *etc*.).

- **DSTI/SPD.** The Committee on Industry, Innovation and Entrepreneurship launched a new project in 2008 regarding the emergence of "global knowledge markets" and the activities of multinational enterprises (MNEs). [See "Innovation within Global Value Chains: The Emergence of global markets for technology," DSTI/IND/WPGI(2008)9.] This group appears to define knowledge markets as being *a priori* global and open. The focus is again primarily on the licensing of patents. It proposes new work on technology balance of payments to understand the size of technology transfer between countries and whether geographical proximity still matters. It will also look at the changing nature of R&D abroad by MNEs.

- **DSTI/ICP.** The Committee for Information, Computers and Communications Policy held a Technology Foresight Forum on The Participative Web in 2007. The participative Web is increasingly important in driving innovation in business**,** research and social activities. More open approaches to information creation, exchange and diffusion are also being taken up extensively in government, the education sector and other public domains. As new models for creation, distribution and use of digital content and information develop, new policy challenges for governments are emerging to provide an environment that enables and supports these developments. The role of Internet-based tools and the participative Web in enabling new ways of innovation in the business sector and new ways for users to participate in information creation, exchange and diffusion is discussed in the Forum documentation (see www.oecd.org/futureinternet/participativeweb). ICCP also held a Ministerial Meeting on the Future of the Internet in Seoul, Korea, which issued a declaration (www.oecd.org/dataoecd/49/28/40839436.pdf) that among other things encourages universities, governments, public research, users and business to work together in collaborative innovation networks and to make use of shared experimental Internet facilities.

- **DAF/CAD.** (Directorate for Financial and Enterprise Affairs/Corporate Affairs Division). The Steering Group on Corporate Governance works on improving the corporate reporting of intellectual assets. It released a report in 2006 entitled *Intellectual Assets and Value Creation: Implications for Corporate Reporting.* The report argues that IA reporting provides the market with information about intellectual assets which improves the exercise of ownership rights and helps discipline management and boards. The report identifies issues that will need to be addressed to enhance disclosure about IAs. It concludes that competition is driving the trend toward the accumulation and better use of IAs and that there is a need for Guidelines in intellectual asset reporting. DAF has ongoing work to develop such guidelines.

16. While all these projects share an interest in the efficient valuation and trade of intellectual assets, there are some crucial differences between them and between the approaches they pursue and the concept of knowledge markets expounded here. The breadth of knowledge goods under consideration varies: most groups are focused on patented inventions rather than the broader set of knowledge intensive goods, services, data, know-how. There is also a difference in terms of the definition of "Knowledge Markets." For many knowledge markets refer simply to the ability to trade or financially leverage patents on an open market. In the context of the Expert Workshop on Knowledge Markets, the focus was rather on new organisational forms that facilitate trade in knowledge intensive goods and services which may not otherwise be traded on an open market. The organisational structure of the "market," the relationship of players, the rules of engagement, and the medium through which knowledge is traded matter. There is a third definition, which is much more narrowly focussed on the electronic marketplaces for knowledge based goods, which provides a mechanism of exchange and again explicit rules of participation. These are not mutually exclusive definitions, but they are importantly distinct from one another. In the life sciences, the international, open trade of patents is well established. Newer are other forms of organisation that facilitate exchange of a broader set of goods and services which have heretofore remained secret or proprietary.

17. Many of the strands of work identified above will be useful in the development of the OECD Innovation Strategy which was mandated by Ministerial level Council meeting in 2007. The Innovation Strategy seeks to identify how the nature of innovation is changing – due to globalisation, the spread of ICTs, improved connectivity and networking, new competitors, new financing and business models, and changing human capital skills and needs – and how policies may need to adapt to meet the opportunities and challenges of today and tomorrow. Clearly, governments have a strong stake in setting up conditions that encourage innovation, and are interested in what knowledge markets are and what role they have in their emergence.

18. At the November 2008 meeting of the WPB, presentations by staff from DSTI/EAS and DSTI/SPD about their work over the next biennium will help delegates identify where WPB might have most added value.

Options for future work within the WPB

19. A number of possible topics for follow on work emerged from the discussions at the Expert Workshop on Knowledge Markets in the Life Sciences. The suggestions focused on five broad topic areas which the WPB may want to explore over 2009-2010. WPB delegates are asked to make consider the themes below, make initial comments as to what themes may be of interest to their countries and discuss by what process the WPB could take any new work forward.

Thematic areas for work

20. Below are six broad issue areas: (A) KM models and knowledge management; (B) Infrastructures; (C) Intellectual Property Rights; (D) Industrial, innovation and regulatory policies; (E) Health policy; and (F) Measurement. Under these headings are particular topics identified during the workshop as needing further work or elaboration. Elements of some of these issues – particularly those under (A) KM Models – will likely be taken up in the Policy Report. Others, for example measurement, are probably best suited to other groups within the OECD or elsewhere. However, the WPB has experience in and a network of experts that could shed light on issues related to infrastructure building, IPRs, health/industrial and innovation policy. WPB delegates should identify which thematic area, if any, they would like to develop further and

A. Knowledge market models and knowledge management

21. *Typology.* The term Knowledge Markets, applied to the life sciences, is relatively new and its definition broad. Existing KMs in health, for one, include public private partnerships, consortia, innovation networks, brokerage facilities, prize mechanisms (*e.g.* Innocentive), data sharing/exchange platforms. A typology of the different sorts of mechanisms and institutions will be helpful to better disseminate what is meant by this concept and to clarify the differences between mechanisms and how they work. Most importantly, it could help policy makers understand what is truly new and useful about their contribution to the innovation process.

22. *Valuation of intellectual assets.* Evaluating the worth of knowledge intensive intellectual assets is inherently difficult. Experts first wanted to know whether there are systematic barriers to scientific collaborations that emerge from difficulty of evaluating the value of IAs. Second, they maintain that improved approaches to valuing and representing knowledge intensive assets in the health sector will facilitate the emergence of Knowledge Markets and increase their impact on the sector. Brokerages, prizes, match-makers and firms that provide outsourced knowledge intensive products and services already exist help put a value to knowledge intensive intellectual assets. Still in development are warehouses or safe brokerage services which act as trusted intermediaries between buyers and sellers. Finally, IT-based methods for representing "knowledge objects" and associated information are also under development. In all these cases, a better understanding of exisiting and emerging methodologies for the valuation and communication of knowledge intensive intellectual assets will help policy makers understand how knowledge markets work and facilitate their development.

23. *Knowledge management.* Knowledge markets are, essentially, mechanisms that enable knowledge management across firms and research organisations. It would be useful to understand how knowledge management strategies are evolving and how knowledge markets fit into those strategies. In short, what is the interrelationship between any new approaches to firm knowledge management and knowledge markets?

B. Knowledge Market infrastructure building

24. *Next generation networking of biomedical infrastructures.* The IT infrastructure is the backbone that allows the networking of disparate databases and repositories. Participants noted that it was important for such infrastructures in the life sciences to be sustainably funded and to stay "technology neutral" so that systems are adaptable and do not limit the future scope of research or collaborations. It might be worthwhile to explore where and how this sort of research infrastructure is successfully being funded and what "technology neutrality" in practice entails. Collaboration with groups that work on IT in the OECD would be required.

25. *Frameworks/Guidelines.* What are the elements necessary to establish KMs and what options are available for addressing the challenges KMs face? A framework to help policy makers involved in the establishment and governance of knowledge markets could help them identify the elements necessary for Knowledge Markets formation and long term success. Governments expressed the need for practical tools and approaches to issues like: IP management, access rules, data and information sharing, privacy and confidentiality, funding. Such frameworks, guidelines or checklists for the creation, management, governance of knowledge markets in the life sciences might address: whether participant interests are aligned, whether there is agreement to the same goals, the balance of participation and investments of parties, whether there are clear public benefits or efficiency gains to be had through co-operation. The framework would also need to address the how to address tiered access policies; shared infrastructures; logistics and operation; quality control and liability issues.

26. The development of effective knowledge valuation and markets within the rubric of competitive (rather than pre-competitive) business practices, so that early return on investments can be generated for currently underutilised knowledge, is clearly desirable if the governance systems in place make this a viable economic and soci-economic prospect. Work needs to be done to articulate expectations and flexibility within such governance systems, especially when considered against the backdrop of the current financial crisis. Co-operation with other parts of the OECD, for example, the Competition Committee, in taking any such work forward could be helpful.

27. "*Safe sand-boxes"* Governments are often key players in the formation of KMs, a source of financial support, as well as knowledge providers themselves. In areas where there is a strong public policy interest, governments can play a catalytic role in bringing diverse parties to the table to discuss new knowledge exchange and formation mechanisms. Areas which might be amenable to the formation of Knowledge Markets include biomarker identification and validation, shared compound libraries, and antibiotics R&D. Is there some interest in exploring whether these issue areas could be addressed through new KMs? Can one *a priori* identify public policy priorities where shared research infrastructures might help meet a public need?

C. Intellectual property rights: access and management

28. *Good practice for Public Research Organisations IP policy and licensing guidelines*. Publicly funded research organisations were criticized at the workshop as often the least amenable to negotiating broad access to their IPRs. Many of the "problematic" patent access cases were patents that originated in universities. Experts noted the need for government policies *vis a vis* research organisations and grantees with regard to how to encourage more sharing and access to publicly funded research outcomes in early stages of research, and suggested this will be helpful for the development of Knowledge Markets.

29. *Shift in definition of pre-competitive research.* There seems to be a shift occurring in the definition of what is deemed precompetitive *versus* proprietary research results and this is affecting the nature of research collaborations. Understanding where the line is drawn, what should go into the public domain, and any trends was seen as important to elucidate. The WPB or other groups might consider a study of the shifting definition of pre-competitive research and how these impact knowledge market formation and any anti-trust considerations.

30. *Database protection.* The protection of databases and their impact on access was briefly discussed at the workshop. Questions raised included: How can the government influence access when open source models are used, as is often the case in bioinformatics? How can government identify what intellectual assets it even owns in open source models of collaboration? What is the impact of database protection on the types of knowledge markets that can be created and their operation?

C. Industrial, innovation and regulatory policies

31. *Bio-pharma industry structure.* Workshop participants discussed the future organisational structure of the health biotechnology and pharmaceutical industry. Some saw the rise of outsourcing and services like Innocentive as part of the move away from fully integrated pharmaceutical companies to a more networked pharmaceutical industry ecology. Others thought, on the contrary, that the complexity and difficult capital investment decisions in the health sector portend well for more a vertically integrated industry structure. Is the emergence of knowledge markets part of a move toward networked pharma? What are the range of potential business models in the health sector? What are some of the innovation benefits of a more networked or "hive" approach to product development (which, for example, might allow a greater number of innovators to participate and include health care providers in the process). What might drive a return to integration? What models best deliver incremental or radical innovations? Finally, how do knowledge markets fit with different business models?

32. *National competitiveness* in science and technology intensive industries remains a central priority for governments, especially given that firms from the emerging economies are beginning to be competitive in the life sciences. What is the scientific or industrial policy rationale for the support of knowledge markets? Are there local returns to participation in the knowledge markets, or are these widely distributed (and if the latter, what is the motivation for government investment in their creation)? Will national competitiveness considerations impact the governance frameworks of KMs? And how might the current financial crisis impact on such considerations?

33. *Global access and technology transfer.* Conversely, as Knowledge Markets become more common, is it necessary to pay attention to broader access and equity issues. Are they indeed open to participants from a wide variety of countries? Do they help or hinder the flow of knowledge across borders? How do lesser developed countries tap into these structures?

34. *Regulatory modernisation.* Knowledge markets, such as the Biomarker Consortium and the C-Path Institute Predictive Testing Consortium, provide a safe haven for industry-government experimentation with new approaches and methodologies for regulatory approvals. Are there further examples of how knowledge markets are being used to reduce costs and risks of the regulatory process. Do they help create common methodologies or better understandings of how to value technologies? How could KMs be expanded for such purposes?

35. *Anti-trust considerations.* Knowledge markets might be both helped and hindered by anti-trust legislation. Where does anti-trust legislation impact knowledge market formation and governance? The nature of the impact of anti-trust considerations could be the subject of further study.

E. Health Policies

36. *Biomedical evidence base.* Will the networking of health and biological data sources, as planned in integrated structures such as CaBIG or the BC Cancer Agency increase the evidence base for efficacy and provide more information to clinicians about treatment options? How and where will knowledge markets have an impact on transparency and availability of clinically useful health information?

37. *Personalised medicine.* Can knowledge markets indeed accelerate the shift to personalised medicines? Do they reduce the costs associated with either research or regulatory approvals and thus make it possible for firms to develop products and services for smaller markets, as in orphan drugs, personalised medicine, or neglected and emerging diseases in developing countries?

38. *Global health challenges.* How do knowledge markets address global – or local – health challenges, as is done in public private partnerships? How is distributed knowledge harnessed through

knowledge markets to address specific public health challenges – for example, AIDS and TB in South Africa? Can this model be expanded?

F. Measurement

39. *Extent of use of KMs in health sector.* Are KMs becoming more common and/or more important in biomedical research? It would be important to start measuring what is indeed happening to get a sense of the extent and impact of knowledge markets. Initial work might include surveys of: *a)* numbers and types of KMs, *b)* number of partners, *c)* funds invested, *d)* citation data, *e)* resultant products/services. More prospective work on types of indicators that could be developed is necessary.

40. *Success metrics.* Work will also be necessary to begin to measure how well knowledge markets in fact work and for what purposes they are best suited as well as what normative policy action might be appropriate to focus success. There is a good deal of work to be done to document that benefits actually do accrue in terms of scientific advance, knowledge management, innovation efficiency, cost savings, regulatory approval, and health outcomes. The major concern at this point is understanding their impact on the innovation process.

Working method

41. Clearly, the discussions at the Knowledge Market workshop were wide ranging and fruitful. The question is how can the WPB leverage the many ideas that emerged from this meeting. Certainly, the first opportunity is the development of the Policy Report which will allow a number of issues outlined above to be explored in somewhat greater depth. Every effort will be made to address the issues raised under A) above at least at first brush. WPB delegate input into other themes they feel could be developed in the Policy Report would be most welcome.

42. Other themes identified above could be added or folded into existing work streams within the WPB. For example, numerous questions focused on IP management and tools. Any overlap with the project on Collaborative Mechanisms for IP management should be exploited. However, new work might be warranted if the WPB were concerned about the protection of a variety of knowledge assets; the theme of how database protection or open access databases will influence knowledge market formation may merit separate consideration.

43. The questions about the changing organisational structure of the bio-pharmaceutical industry, and new approaches to the valuation of intellectual assets, might be a good topic for consideration by the Task Force on Biomedicine and Health Innovation. Similarly, the use of knowledge markets as a way to pursue (1) regulatory change and (2) public health goals may also be suited to the TFBHI in 2009-2010. One option would be for the TFBHI to consider these themes and their interest at its next meeting.

44. However, there are also questions raised at the Knowledge Markets workshop that might merit consideration on its own. For example, work on the development of guidance for knowledge market creation and on the application of such guidance to public health priorities (the "safe sandbox" idea) could be challenging but worthwhile avenues of work for the WPB. These two themes build on WPB strengths in convening diverse actors, research infrastructure networking, and guideline development. However, exploring these themes further would require convening an expert level steering group to explore their feasibility and methodology.

45. Finally, as none of the above topic areas have been costed, at this point, the WPB is being asked to indicate preliminary preferences about what sort of work it would like to see included under the 2009-2010 PWB. Some topics may be referred to other working groups or steering groups for their consideration. Others may require the formation of a steering group to take on.

Action points:

- **Discuss** the thematic areas - or subheadings - which are of interest to your country to pursue in 2009-2010;

- **Agree** a process for developing any new projects related to Knowledge Markets and **consider** whether a small expert steering meeting should be held to evaluate worked-up options and report back to WPB.

ANNEX1: AGENDA OF THE OECD EXPERT WORKSHOP ON KNOWLEDGE MARKETS IN LIFE SCIENCES

Held at the National Academies of Science

Washington, D.C., United States

16-17 October 2008

Morning Day 1, 9:00 to 13:00

Morning Chairman: Dominique Guellec, OECD, France

9:00 Introductory Remarks

Richard Johnson, Arnold and Porter, Global Helix LLC, USA

9:15-10:45 Session 1: Intellectual assets in health: current inefficiencies and future trends

Underused and undershared knowledge in bio-medicine – Fiona MURRAY, MIT Sloan School of Management, US

Breaking the Rosetta Stone: Patient Data as the Key Asset to Accelerate Medical Research – Greg SIMON, FasterCures, US

Intellectual assets and information asymmetry in the bio and pharmaceutical industries — Jonathan KLEIN-EVANS, MedImmune

What is new about markets for technology: the recent business and economics literature - Ashish ARORA, Carnegie Melon University, US

What are the intellectual assets of the health and biomedical sector? How are these identified, reported, valued and exploited? Are there inefficiencies in the way existing intellectual assets are used in the health sector? Are certain intellectual assets under-used or under-shared? What are the various types of knowledge that are currently being underused and might when aggregated have added-value. What are the types of knowledge that are traditionally held proprietarily but might be shared if a market existed? This session will give an overview of the types of knowledge, be it data, products, know-how or networks for which the existence of a knowledge market would open new possibilities to both the suppliers and potential users of such knowledge.

COFFEE BREAK, 10:45-11:15

11:15-12:30 Session 2: Knowledge markets in theory and practice – what are they and what do they do?

What are knowledge markets? Problems and paradoxes - Brian KAHIN, University of Michigan, and Computer & Communications Industry Association, US

Tapping a Network: Approaches and Applications - Alph BINGHAM, Co-Founder and Member Board of Directors, InnoCentive, US

Intellectual assets – creating national wealth in the 21st century - Claude RUBINOWICZ, Chief Executive, Agency for Public Intangibles of France (APIE), France

How are Knowledge Markets defined and how do these modes of organisation improve the management and exploitation of different intellectual assets? What types of knowledge markets exist already and in which industries? What lessons can be drawn about their applicability to the health sector?

This session will explore the different modes for making available, valuing and trading knowledge and information including: warehouses, clearinghouses, auctions, brokerages, pools. It will draw on the experiences in other sectors (*e.g,* information technology, engineering IP, journalism). Discussion will explore the possible benefits of knowledge markets: Do knowledge markets increase transparency; facilitate learning and technology transfer; reduce development costs; improve access to capital; facilitate the entry of new or smaller enterprises? Do they help investors evaluate a company's strategy and performance, or improve firms' ability to capitalise on or otherwise create value from presently under-used assets; or help achieve public goals such as improving transparency of research results.

LUNCH – 12:30-14:00

Afternoon Day 1, 14:00 to 18:00

Afternoon Chairs: Stephen Merrill, National Academy of Sciences, USA and Bénédicte Callan, OECD

14:00 – 15:15 Session 3: What is the policy interest in Knowledge Markets for health?

Reduced drug development costs and improved clinical care – Joe FECZKO, Chief Medical Officer, Pfizer, US

Applying genomics to health care: drug development, treatment avoidance – Sam ABRAHAM, Vice President Strategic Relationships, BC Cancer Agency, Canada

The TI Pharma strategy –Willem de LAAT, TI Pharma, NL

Why is the emergence of knowledge markets in health of interest to OECD countries and beyond? What are the potential economic spill-overs or contributions to public health that knowledge markets can help achieve? What new approaches to the exploitation of intellectual assets are already emerging amongst public research institutes, pharmaceutical and biotechnology firms, journals? What are the advantages or benefits promised by these new approaches – from a commercial or public health perspective? This session will focus on existing trends in health innovation and the new ways of pooling, accessing and trading, and creating value out of knowledge.

15:15-16:45

Session 4: Existing infrastructures for knowledge pooling and sharing

Overview of NCI/NIH initiatives for knowledge access and use – Ken BUETOW, NCI Chief Information Officer, Director of the Center for Bioinformatics, NCI

Collaborative knowledge networks for physicians - Iwan von WARTBURG, University of Hamburg, Germany

Clinical trials: registration, results reporting, and data sharing – Jerry SHEEHAN, National Library of Medicine, US

The Biomarker Consotrium and the Genetic Association Information Network – David WHOLLEY, Biomarker Consortium, US

A variety of "pre-competitive" consortia in the life sciences have recently been created – many of these with the involvement of the NIH/NCI in the US. These seek to pool research results, and in some cases, even create standards for use in regulatory approval processes. The pooling of knowledge and the interoperability of different data sources can help accelerate the delivery of new technologies and therapies. There is a movement to extend the pooling of R&D resources further upstream. What can be learned from present experiences? What knowledge resources that were once proprietary could one envision sharing more broadly? What sorts of knowledge have more value when aggregated, integrated and made interoperable? What sorts of arrangements are emerging that appeal to the private sector?

COFFEE BREAK – 16:45-17:15

17:15-18:00 Session 5: Niche brokering: finding new users for old knowledge

Repurposing technologies with low NPV for infectious disease treatment - Wendy TAYLOR, Bioventures in Global Health, US

How pharmacogentics may bring new life to failed drugs - Wayne ROSENKRANS, Personalized Medicines Coalition, US

This session will discuss how proprietary knowledge that has no immediate value to the owner (for example older molecules or failed clinical trial data) can find new markets or can be repurposed, shared and exploited, for different uses or markets leading to new products and services. Services are emerging to match the holders of such knowledge with those that have a new use for it. What are the challenges niche-brokers have to address? Is such brokering become more common; is there data on the frequency of its use; and is it scalable?

COCKTAIL – 18:00

Morning Day 2

Morning Chairman: Lisa Drouillard, Health Canada

9:00-10:30 Session 6: The future of knowledge markets: opportunities and challenges

The future of sharing access to chemical libraries - Paul WYATT, Director of Drug Discovery, University of Dundee, UK

Algorithms, data structures and web computing for data mining in biomedicine – Jonas ALMEIDA, Dept of Bioinformatics and Computational Biology, University of Texas, MD Anderson Cancer Center, US

Pooling toxicology data and drug screening tests - Federico GOODSAID, Office of Clinical Pharmacology, FDA, US

Looking forward, what are the factors pushing or impeding the greater exchange of knowledge in the health sector? Certainly, some types of data is worth more when aggregated than the sum of its parts and all stakeholders would benefit from a database that pools the data. However in some cases the competitive value of the data to the owner prevents it from being shared or traded without the appropriate incentives or regulation in place. In other cases, operational difficulties such as asset valuation, interoperability of data, and information asymmetries make data pooling difficult. In this session speakers are asked to discuss where in the health domain the existence of knowledge markets may be tough but possible. What types of data, information and knowledge might be ripe for pooling or exchange and what types are unlikely to ever be? What factors could push the creation of knowledge markets forward? What policies or incentives might help play helpful/a role?

COFFEE BREAK – 10:30-11:00

11:00-12:15 Session 7: Application of Knowledge Markets beyond Health

A knowledge market prototype: from conception to execution -- Wolfgang MAASS, Director of the Research Center for Intelligent Media, Hochschule Furtwangen University, Germany

Knowledge markets and IT in the life sciences - Sylvia SPENGLER, Division of Information and Intelligent System, National Science Foundation, US

Just like the greater exploitation of knowledge can create added value and increase efficiency in drug development and health outcomes, so too might the trading and sharing of knowledge create greater value along the industrial biotechnology value cycle, or foster innovation in the development of synthetic biology. This session will explore where and how knowledge markets are applicable in biotechnology sectors beyond health.

LUNCH – 12:15-13:45

Afternoon Day 2, 13:45 to 17:30

Afternoon Chairman: Anita Eisenstadt, Department of State, USA

13:45-15:00 Session 8: What are the forces and incentives facing knowledge markets?

Measurement, reporting and valuation of intellectual assets: the investor view -- Alexander WELZL, Commission on Intellectual Capital, European Federation of Financial Analysts Societies (EFFAS), Austria

Intellectual Capital Reporting – two business cases from healthcare and bio-medicine: Michael KIMBROUGH, Harvard Business School, US

Securitisation of clinical trials - Peter BROWN, SecureAid, UK

Moderated discussion with experts about future trends in the valuation of pharma/biotech and their impact on knowledge management. Changes underway include pressure from the financial communities for more granularity in intellectual asset reporting which may lead to a better understanding and, ultimately, use of intellectual assets. Networked approaches to health product

development are also breaking down the value chain into discrete modules whose products and services can increasingly be traded. As these trends continue, new business opportunities open up for facilitating the exchange and trade of biomedical knowledge and information.

What pressures, financial or otherwise, are driving the creation of markets for knowledge intensive intellectual assets and what are the challenges and barriers to the trading of knowledge assets? Is better knowledge management important in valuing companies? What interests do scientists, investors, policy makers and the industry have to increase valuation, access to and interoperability of knowledge assets, and how do these interests align or misalign?

COFFEE BREAK, 15:00-15:30

15:30-16:30 Session 9: What can Governments do?

Moderated panel discussion with a selection of representatives across the OECD.

Bénédicte CALLAN, Biotechnology Division, OECD

Lisa DROUILLARD, Health Canada, Canada

Rick JOHNSON, Arnold and Porter, USA

Bart WIJNBERG, Ministry of Health Welfare and Sport, The Netherlands

Winston BAATJES, Department of Science and Technology, South Africa

What can governments do to help the emergence of knowledge markets move forward? What might impede their creation? What is the role of competition policy, regulatory policy, accountancy standards, or the articulation of industry standards? Should governments encourage such structures or be involved in setting up prototypes? How can governments facilitate policy harmonisation across borders in areas such as patient protection, biorepositories and standards for clinical trials? How and where could the public sector be most useful?

16:30 – 17:00 Concluding Remarks from the OECD

ANNEX 2 – WORKSHOP ISSUES PAPER

Introduction

In the health sector, new mechanisms are emerging to trade an increasing variety of knowledge intensive assets (*e.g.* data, materials, expertise, services). This OECD Workshop will explore what these "Knowledge Markets" are and what benefits they bring to health innovation and health outcomes. It will identify what types of products, materials, data, information, and know-how can create added-value when exchanged or traded. It will describe the mechanisms which try to facilitate such exchanges. The Workshop will also address what forces are driving the creation of knowledge markets; the factors that might limit their development; and their application beyond the health sector.

The purpose of the workshop is to help government policy makers understand the forces behind the development of Knowledge Markets, their possible impacts on innovation, and the role that public policy can play in facilitating their emergence.

What are Knowledge Markets?

In a recent book on the biotechnology industry, Harvard Business School Professor Gary Pisano concludes that the complexity of knowledge integration suggests that "the sector needs mechanisms to bring specialists from different disciplines together and to facilitate the flow of information across organisation and disciplinary boundaries." Knowledge markets aim to do just that; they encompass a number of different mechanisms, or marketplaces, where buyers and sellers trade different knowledge intensive goods and services. In the life sciences such tradable assets could for example be scientific data such as the outcome to clinical trials or toxicology data, but could also include experience from surgical cases which could be exchanged on a platform, or the matching of patent holders with interested licensees through a knowledge broker.

The stimulus for this topic came in a 2006 OECD workshop on Emerging Research Models where participants discussed the flow of information in biomedical research and identified a need for greater transparency in order to accelerate health innovation. Participants at that meeting agreed that public and private research organisations needed to move away from the prevailing practice of keeping data proprietary and, instead, develop new kinds of markets through which companies, universities, regulatory agencies, and others could exchange valuable information and data that now are presently treated as proprietary.

The term "Knowledge Markets" is for the purposes of this workshop loosely defined to encompass a number of different mechanisms and platforms whose goal is to increase access to existing knowledge. Buyers and sellers can pool or trade data, information, contacts and know-how. Intellectual property (IP) exchanges and patent pools, consortia, networking, matching or brokering services, clearing houses, knowledge warehouses and auctions all fall into this broadly defined concept. They are alternative ways of managing and deriving value from intellectual assets. What they have in common is that they are "mechanisms for enabling, supporting, and facilitating the mobilisation, sharing, or exchange of information and knowledge." (Some of these mechanisms focus on intellectual property and are discussed in the OECD report on Collaborative Mechanisms, see DSTI/STP/BIO(2007)8/REV1.)

While this form of pooling, trading and sharing intellectual assets is not an entirely new concept, in the life sciences these are relatively recent phenomena. Some of the more pioneering health initiatives have emerged in a range of different technical domains and at different points in the innovation cycle. In other industries, such mechanisms have a slightly longer history – mainly in the IT where information is

digitized. For example, a number of Internet-based knowledge markets have recently sprung up, which exchange knowledge through a question-answer service, either with or without the monetarisation thereof (*e.g.* Wikipedia Reference Desk, and now defunct Google Answers). In the bio-pharmaceutical industry the best known examples are collaborative mechanisms for intellectual property (IP pools, clearinghouses) and consortia for pre-proprietary knowledge (Biomarkers and Synthetic Biology).

What is driving the development of Knowledge Markets?

A number of key drivers have been changing the environment for innovation in the health sector. These drivers are pushing research organisations to think creatively about the way they manage and capture value from existing knowledge, be it in house or external. There is a substantial literature – and a considerable diversity of opinion – about what are the most important of these drivers, with the following elements emerging:

The dominant role of S&T and innovation in creating growth and wealth is now widely accepted.

Innovation is becoming increasingly knowledge-driven: a shift towards evidence–based innovation.

The organisation of research is changing incredibly rapidly – driven by informatics and the relatively new notion that collaboration and sharing of knowledge can be more than a zero sum game.

Rapidly improving connectivity – and the development of platform technologies/ standards - as globalisation accelerates.

Meantime, changes to markets, the competition environment and technology are happening at a far faster rate than ever before – so continuous and continual learning and adaption are essential.

Profound efforts are under way to improve valuation of assets and enterprises based on knowledge and development of innovative financial models (and framework governance).

The rapid pace of scientific and technological advancement in the life sciences, the complexity and heterogeneity of knowledge relevant to health innovation across multiple fields and subfields and the need to integrate the vast amounts of both scientific and clinical data all combine to create challenges for achieving the interoperability, knowledge integration and accumulation necessary to harvest the full benefits of the existing knowledge base. Knowledge Markets may help address some of these challenges.

Policy interest in Knowledge Markets

The existing norms of IP protection and the nature of competition in the health and biotechnology related industries is such that vast amounts of data, information and knowledge created throughout the health innovation cycle is largely held proprietary. While some amount of property rights are necessary as an incentive for innovation, there remains a substantial amount of knowledge and other intellectual assets that are generated which are not core business and could be exchanged (for money or for other knowledge assets or services) at terms beneficial to both the provider and consumer of such knowledge.

Achieving greater access and exploitation of existing knowledge, by facilitating the trading and sharing thereof, would increase the efficiency of the health innovation cycle and potentially deliver a number of positive health and economic outcomes. For example, creating consortia or knowledge commons for pre-competitive knowledge can speed up the pace of innovation in early stage technologies such as synthetic biology, and perhaps avoid or reduce patent thickets or anti-commons which deter innovation. By sharing knowledge about failures, or know-how about regulatory procedures, drug development costs might be reduced. Knowledge markets may also bring opportunities to health care

provision as such, by paving the way towards personalised medical care (for example if data from 'failed' drugs are repurposed with pharmacogenetic research). The benefits of more efficient and effective exploitation of our existing knowledge resources could thus be harnessed not only by the biotech and pharmaceutical industries, but also by patients, health care providers, the financial investing community and – if used to address global health challenges – to society at large.

Underused and 'Undershared' knowledge

At present it is primarily vertically integrated companies, including biotechnology and pharmaceutical firms, who scan, integrate and build value from in-house knowledge assets. Beyond that the inter-relationships between firms through the explosive increase of outsourcing, as well as mergers, licensing and other forms of collaborations, are allowing for the exchange and value-creation from out-house knowledge assets. Yet, increasingly, experts are suggesting that present business strategies and even the organisational structure of the bio-pharmaceutical sector are not as productive as might be possible.

A core element of productivity is the efficient management of intellectual assets. Much of the present literature is focused on in-house knowledge management inefficiencies, with little attention paid to the potential that such knowledge can derive if employed out-house. Knowledge markets address precisely this inefficiency; the `underuse' and 'undersharing' of the large amounts of data and information created throughout the innovation cycle. In some cases knowledge that is held privately may not be of value on its own, but could have added value when aggregated into databases. In other cases old data or data about failures may be worthless to its owner, yet significant in different research tracks in other companies, perhaps even in entirely different domains. There is also the type of knowledge or data that is of competitive interest to the holder, but that, when pooled is worth more to the various stakeholders than the sum of its parts (*e.g.,* SNPs and biomarker consortia). This latter type of knowledge asset will likely be the hardest to create a market for, as the difficulty of asset valuation, and the inherent competition of the industry present challenges to the creation of a viable market for exchange.

The types of under-developed or under-utilised information in health innovation might include:

- Pre-competitive knowledge currently held proprietary that if aggregated, integrated and made interoperable and searchable could yield new information building perhaps in particular, on experience from the human genome project and the SNPs consortium.

- Information associated with failed and abandoned projects (which if companies were able to market some portion of might help recoup some of their research investments). For example, failed drugs might be repurposed and find a new market in pharmacogenetics research.

- Databases that are presently maintained in-house but could be scaled and shared for mutual benefit, such as for example toxicology data.

- Intellectual assets that could be of higher value out-of rather than in-house. For example, developing a means by which firms could access one-another's' compound libraries.

- Proprietary know-how relating for example to the regulatory framework, or clinical trial software, can be of value and therefore find a market out-house.

- Promising lead molecules which are not taken forward into Phase II trials due to lack/cost of capital or poor market expectations, where approaches to securitize late stage development could have value

The expert workshop will address what kind of knowledge is being underused in the life sciences and what sorts of new institutions and organisational mechanisms for creating value could emerge to exploit this knowledge. If one deconstructs the innovation cycle into modular units, is it possible to envision different sorts of knowledge markets that will buy, sell, trade the modules more efficiently than is done now? It may be, for example that certain discrete and fundable intellectual assets would be worth more – both in monetary and scientific value – if they were traded within a knowledge market rather than used in-house.

Challenges to creating knowledge markets

This approach for more sharing of data is aimed at abetting the development of programmes or potential products that otherwise would languish. The concept of knowledge markets represents a major shift from traditional strategies that emphasize safeguarding IP and toward more connectivity and sharing of IP. As such, it necessitates a cultural shift – as well as a competitive and legal shift – on the part of various players within the biomedical research sector, a change that is fraught with difficulties. Obviously, greater exchange of data and knowledge, if it can indeed be arranged, would not be all-encompassing because the promise of IP exclusivity and the economic benefits accompanying product exclusivity are a major driving force behind health innovation. The challenge will be to identify those intellectual assets for which an economic incentive for their exchange would exist, provided that the necessary market platforms are created.

One suggestion made at the Emerging Research Models workshop was to find non-threatening - non core business - ways of implementing this idea on a pilot basis. Some such consortia for sharing pre-competitive data already exist, notably in the development of biomarkers and synthetic biology , and these 'neutral sandboxes' should be examined to derive what dynamics allow for them to work, and how this might be extrapolated to other areas of research and types of knowledge. Similarly, valuable lessons can be learnt from industries where knowledge markets have a tangible existence, such as in electronic information exchange, as well as from existing initiatives with similar objectives in the life sciences (*e.g.* increasing transparency, pooling resources, matching supply and demand).

There are likely to be plenty of practical and policy obstacles to overcome before such knowledge markets become widespread. For one, national antitrust laws restrict certain kinds of cooperative exchanges between companies in the same market niche. For another, for-profit companies as well as the broader research community, are intensely competitive and very much depend on this culture to thrive. This competitiveness is likely to be further accentuated as new companies from developing countries begin to enter research intensive industries and offer their research and development services to companies in Europe and North America.

Even with a mindset and willingness of private and public researchers to increase the exchange of knowledge assets, there remain a number of practical difficulties to overcome. In order for a monetarised market to be functional it must be possible to assess and report the value of a knowledge asset. While some international initiatives pushing for intellectual capital reporting exist, they are far from common practice and are not internationally harmonised. Information asymmetries between knowledge holders, brokers and potential buyers further exacerbates this issue. The lack of interoperability between data sets might also present another practical difficulty that could hamper the pooling or exchange of these assets, even when such exchange would be mutually beneficial to the various stakeholders.

Mechanisms and incentives for trading knowledge

The market values intellectual assets – and thus knowledge. This means that any information asymmetry between Chief Knowledge Officers, and others taking a technology appraisal approach to

valuing assets, and the market analysts that react to such appraisals, needs to be narrowed if market values are to match the "real" value of innovation and the S&T that underpins innovation.

Better guidelines for the reporting of knowledge and intellectual assets might help – but *prima facie* policy needs to drive the narrowing of such information asymmetry (though it is recognised that public policy may intentionally place a different value on innovation in some technology areas than an open market might – but in such cases policy intervention needs to be goal driven and transparent). The existence of mechanisms that allow the market to reflect the true value of innovation and the knowledge that underpins it would open new financial opportunities both for knowledge asset owners (by way of employing their assets to attract capital) and investors (through more transparency in asset reporting and valuation).

The emergence of mechanisms to share and trade knowledge creates a new type of market in which knowledge is the product under demand. This opens up new opportunities for existing players in the life science industry, as well as for potential new entrants. Owners of knowledge assets have a new, and potentially earlier source of income by selling or licensing data or patents. On the other hand, there will be a need for knowledge brokers to match the suppliers and users of the knowledge that is 'on the market'. Some such niche brokers have already emerged, for example in the matching of targeted philanthropic funding with appropriate research projects, or in the licensing of older and failed lead molecules.

Another shift that is driving the emergence of knowledge markets is the push for greater transparency of publicly funded research and its outcomes. With the pressure to make clinical trial data publicly available, some of the interoperability and transparency issues that present a challenge to knowledge pooling and trading are alleviated, while the public research space becomes more transparent and accessible.

Policy advice to OECD member countries

Knowledge markets are about improving knowledge creation and development as well as about capturing returns on that knowledge. For OECD countries the key issues are whether there exist policies and incentives which could encourage firms to participate in different markets where previously privately held data and information can be valued, pooled and exchanged. For the moment, the policies that encourage this transition are not well understood. Indeed, what the role of government could be needs exploring.

The OECD workshop on Knowledge Markets in the Life Sciences will include participants from the private sector, the public research community, the financial community and government policy makers. Beyond simply describing current trends in the development of different types of knowledge markets, this workshop seeks to better understand where such mechanisms are applicable and for what purposes. It will ask participants to discuss whether knowledge markets help improve health innovation and if so what role governments might play.

Specifically, the workshop will explore:

- The inefficiencies of the present health innovation cycle are and how Knowledge Markets might address these.
- How to better commercially exploit knowledge, theory and experience.
- What kind of knowledge is already shared or pooled and what kind of knowledge still leaves potential for further value capture?

- How various stakeholders could benefit from increased knowledge trading?
- What are the different modalities for sharing?
- How is the knowledge reported and valued?
- Who participates? Is the community open or closed?
- What infrastructures – scientific, informational, regulatory, legal – are necessary?
- What are the challenges to building knowledge markets and how might they be overcome?
- What policies or incentives might encourage experimentation with knowledge markets?

ANNEX 3: SUGGESTED BACKGROUND READING LIST

The following is a reading list suggested for participants at the OECD Knowledge Markets Workshop. It includes articles from academic and industry journals, the popular press, as well as official reports. All of these papers shed light on the question of what is driving changes in knowledge management in the health sciences and what role knowledge markets likely to play in future business models and industrial organisation. It was not meant to be exhaustive, but simply presented a number of papers the OECD Secretariat thought might be of use to participants.

Session 1: Intellectual assets in health: current inefficiencies and future trends

Bingham, Alph (2006). "Whither Pharma," *Drug Discovery World | Business*, pp 9-15.

This short article focuses on the pharmaceutical industry, explaining why the blockbuster model may be faltering and the economic, technological and social factors driving changes in that business model. It argues that the likely future organisational structure of firms will rely on monetisation and the ability to recoup investment within shorter cycles by offloading risk into a marketplace. Alph Bingham is speaking in Session 2.

Session 2: Knowledge markets in theory and practice

Teece, David (1998). "Capturing Value from Knowledge Assets: The New Economy, Markets for Know-How, and Intangible Assets," *California Management Review*, 40:3, pp. 55-79.

This relatively old academic overview of intellectual asset trading which identifies its inherent difficulties. It provides a useful taxonomy of the types of knowledge that exist in a business context. It is not optimistic about the functioning of knowledge markets, but maintains that they might work better in the pharmaceutical and chemical sectors than, for example, in electronics.

Arora, A., Forsfuri, A., Garmbardella, A. (2001). "Markets for Technology and Their Implications for Corporate Strategy," *Industrial and Corporate Change*, 10:2, pp. 419-451.

An academic article that discusses how markets for technologies, ideas, knowledge and information – which have become more common - influence corporate strategies. For start-ups markets for technology make a focused business model more attractive and for industries, and may lower barriers to entry thus increasing competition. Ashish Arora will present in Session 1.

Apostolou, D. *et. al.,* (2005). "Challenges and Directions in Knowledge Asset Trading." International Journal of Intelligent Systems in Accounting, Finance & Management, Volume 13, Number 1, March 2005, pp. 1-15(15).

This paper addresses challenges in the exchange and trade of knowledge. Electronic knowledge marketplaces are emerging to address the opportunities and risks in the purchase and selling of knowledge in the business-to-business environment, the need for supporting long-lasting relationships of knowledge exchange and the requirement for facilitating virtual community contexts where knowledge seekers can find suitable knowledge providers. It describes the business challenges associated with the design of an Internet-based knowledge marketplace using INKASS as an example.

Kahin, Brian (2008). "The patent bubble… still growing," *The Huffington Post*, September 26, 2008. http://www.huffingtonpost.com/brian-kahin/the-patent-bubble-still-g_b_129232.html

This is an Internet news article about the IT-centered patent bubble, its manifestations, impacts and possible remedies.

Session 3: What is the policy interest in Knowledge Markets for health?

Carey, Benedict (2008). "Antidepressant Studies Unpublished," *The New York Times*, 17 January 2008. http://www.nytimes.com/2008/01/17/health/17depress.html

This is a press article about an antidepressant study based on previously unpublished trial results. It addresses the issue of lack of transparency in clinical trials and how studies with negative outcomes tend to remain unpublished, creating a bias towards positive results. The need to increase transparency in research outcomes is one of the policy interests behind the push for knowledge markets.

BioVentures for Global Health (2007). *Closing the Health Innovation Gap: A role for the Biotechnology Industry in drug discovery for neglected diseases.* http://www.bvgh.org/documents/InnovationMap.pdf

This is a report that details the core capabilities of different actors in the development of new drugs for neglected diseases. It identifies an "innovation gap" and some of the technologies, resources, and expertise that could be better accessed and harnessed for researching these diseases. It contends that scientific tools and molecules exist to initiate drug discovery in malaria, tuberculosis and trypansomal diseases but there are hurdles to increased biotech firm involvement which will require new approaches and partnerships among actors. Creating a better match between existing knowledge and potential users to address global health challenges is another policy goal. Wendy Taylor, Executive Director of BVGH, will discuss some of these strategies in Session 5.

Callan, Benedicte. and I. Gillespie (2007). "The path to new medicines," *Nature*, 449, pp. 164-165.

A short article summarizing the conclusions of a political conference on the "push and pull" mechanisms used to address global health challenges. It discusses the need for a more open and collaborative innovation system, functioning within the current IP regime, which could lower barriers to entry and create new incentives for private sector collaborators. The evolution of the current health innovation system is discussed the context of neglected and emerging infectious diseases but it is relevant to health innovation more broadly.

Session 4: Existing infrastructures for knowledge pooling and sharing

Buetow, Ken (2008). "Heading for the BIG Time: The NCI's bioinformatics network, caBIG, integrates cancer data from all over the US," *The Scientist*, 22:4, pp. 60-66.

This article is about caBIG, NCI's collaborative research platform for cancer research. Relevant to a number of sessions, it addresses the questions of why there is a need for such platform for collaboration and exchange; how the project was conceived and piloted; what the capabilities of the system are; and how it helps advance cancer research.

Session 5: Niche brokering: finding new users for old knowledge

Wang, S.S (2008), "Genetics may bring new life to failed drugs," *The Wall Street Journal*, 24 March 2008. http://online.wsj.com/article/SB120631682077958247.html

This press article addresses how 'failed' knowledge, such as drugs that were not brought to the market, can be repurposed as targeted medicines, and how genomics can help provide information about the cause of failure. It provides an example of a potential knowledge market.

Session 6: The future of knowledge markets: opportunities and challenges

Gassman, O. and Reepmeyer, G. (2005). "Organizing Pharmaceutical Innovation: from Science-based Knowledge Creators to Drug-Oriented Knowledge Brokers." *Organizing Pharmaceutical Innovation*, 14:3, pp. 233-245.

An article on how pharmaceutical R&D strategies are responding to the decline in R&D productivity. It emphasizes new firm approaches to technology management, R&D internationalisation, and the use of open innovation modes.

Lettl, Christopher (2005). "The emergence of radically new health care technologies: Inventive users as innovation networkers." *Technology and Health Care*, 13, pp. 169-183.

An academic paper on the role users play in the emergence of new health technologies based on the case of a virtual innovation network of surgeons who identified partners with complementary knowledge bases to help transform radically new ideas into physical prototypes that could be used in practice.

Pharma Futures (2007). *Prescription for Long-term Value*.
http://www.sustainability.com/downloads_public/pharmafutures/pf_report1.pdf

Outlines the findings of a dialogue between pharmaceutical industry executives and major institutional investors on how the health sector can better deliver long-term value to shareholders and consumers. It identifies changes in R&D productivity, payer pressures, and emerging markets as shaping the market environment and firm strategies.

Session 8: What are the forces and incentives facing knowledge markets?

Bismuth, A. and Kirkpatrick, G. (2006). *Intellectual assets and value creation: implications for corporate reporting.* OECD, Paris. http://www.oecd.org/dataoecd/2/40/37811196.pdf

This report argues that providing the market with information about intellectual assets improves the exercise of ownership rights and helps discipline management and boards. It identifies the issues that will need to be addressed to enhance disclosure about IAs. It concludes that competition is driving the trend toward the accumulation and better use of IAs and that there is a need for Guidelines in IA reporting.

OECD Policy Brief (2007). *Creating Value from Intellectual Assets.* OECD, Paris. February. http://www.oecd.org/dataoecd/8/45/38194512.pdf

This policy brief looks at how a better understanding and improved disclosure of investments in intellectual assets, as well as diffusion of best practices, would benefit managers, investors and policy makers.

Kamiyama, S., J. Sheehan and C. Martinez (2006). *Valuation and Exploitation of Intellectual Property*. OECD STI Working Paper 2006/5, OECD, Paris.
http://www.oecd.org/dataoecd/62/52/37031481.pdf

This OECD report focuses entirely on intellectual property but it gives an excellent overview of the importance of valuing and exploiting IP, both internally and externally, and the development of technology markets. It examines approaches to the valuation of patents and the policy initiatives undertaken by OECD countries to foster patent valuation and exploitation. Jerry Sheehan will speak in Session 4 of the workshop.

Jarboe, Kenan Patrick (2008). "Building a Capital Market for Intangibles," *Intellectual Asset Management*, June/July, pp. 30-35.
http://www.athenaalliance.org/pdf/BuildingaCapitalMarketforIntangiblesIAM30.pdf

This article argues that intangible assets are an untapped source of capital and an unrecognized opportunity for investors. But creating robust capital markets for intangibles is challenging. The author identifies policies that could facilitate their creation.

ANNEX 4 -- DRAFT CHAIRMAN'S SUMMARY OF WORKSHOP MESSAGES

What are Knowledge Markets?

- KMs are a catch-all term to describe the formal mechanisms and institutions that facilitate access to an use of a wide variety of types of knowledge within the biomedical community. KMs make knowledge available, accessible, usable and sometimes tradable.
- KMs cover a wide variety of types of data, information and knowledge, including: databases, services, know how, materials, compounds, software, methodologies, expertise, as well as any other patentable inventions. What is traded is a combination of tacit and implicit knowledge.
- What is new is the distributed, virtual and sometimes quite disparate nature of the knowledge resources that are brought to the table and the sophisticated use of information technologies to flexibly interconnect them in order to advance science and technological development.
- The elements of knowledge within KMs are sometimes, but not always, individually valued or monetised. While there is often a "pay to play" requirement, the individual assets brought to the table may not be explicitly valued.
- KMs are institutions or structures with formalised rules of engagement amongst diverse parties including traditional competitors (*e.g.* academia, private research organisations, biotech/pharmaceutical firms, regulatory agencies, individuals), which are designed to leverage multiple sources of external knowledge, and are:
    - Collaborative
    - Research focussed and translational
    - Not necessarily precompetitive (*e.g.* Innocentive, brokerages)
    - Reliant on digitisation and a networked IT infrastructure to support access/use of knowledge goods
    - Networked and delocalised
    - Not fully "open" or public
    - Often Pay-to-Play
    - Time & purpose limited
    - Both bottom up and top down – one or the other, but not both - in terms of the aims of research outcomes
- KMs include public private partnerships, consortia, innovation networks, brokerage facilities, prize mechanisms (*e.g*. Innocentive), data sharing/exchange platforms (*e.g*. caBIG). [They probably do not include TTOs where each transaction is unique or patient information exchange websites where there is no formalised mechanisms for transferring data, information, knowledge for the purpose of improving innovative process, though exceptions include "patients like me" and EHR databases used in research.] [Typology and/or list of KMs to be completed]
- KMs have so far typically addressed areas where there are collective action problems, the under-provision of goods and services which might have commercial value or provide a public good if

disparate knowledge could pooled from multiple sources and used. Current examples are found in cancer, infectious diseases and biomarkers.

Are KMs becoming more common, more important in biomedical research?

- Biomedical research system is under enormous pressure as it has become far more diverse, has accommodated many new players globally, has distributed its knowledge intensive resources widely, is awash in information, and has become costly to maintain. Biomedical research institutions are under strain and are looking for new ways of working.
- KMs are on the rise throughout health innovation cycle (from precompetitive R&D through to shared methodologies for meeting regulatory requirements). They may be more common in certain disease or issue areas (Infectious Disease, Biomarkers (personalised meds), and cancer), though it is not clear why this is the case.
- The value of knowledge markets mechanisms as responses to pressures on the biomedical research system seems to be universally acknowledged.
- How big a boom this is or will become, and how radical a departure from past exchange practices, remains unclear. It would be important to start measuring what is indeed happening to get a sense of the extent and impact of knowledge markets. Initial work might include surveys of: *a)* numbers and types of KMs, *b)* number of partners, *c)* funds invested, *d)* citation data, *e)* resultant products/services. More prospective work on types of indicators that could be developed is necessary.

What are the motivations and incentives for firm and research organisation participation?

Motivations for participation vary by type of actor (firms, PROs, individual researchers, academia) but include:

- Reductions of transaction costs, research costs, duplication
- Risk sharing
- Place to address lacunas and/or unmet needs (*e.g.* shared novel methodologies, novel datasets such as compound libraries).
- Public Acceptance
- Prestige
- Intellectual challenge
- Norms and peer pressure
- Regulatory approval co-evolution
- Safe haven experimentation with new (more open or networked) research strategies and business models

What are the elements necessary to establish KMs?

- Agreement by all parties to a common set of goals
- Clear public benefit
- Balanced particpation agreed at high level
- Articulated goal of being more efficient
- Policies and governance structures set up in advance which address:
    - IPRs
    - Privacy/Confidentiality
    - Human subjects

- Access

What are the challenges in the establishment of KMs?

- Long term sustainable funding (for establishment and maintenance)
- IPRs
- Privacy/confidentiality, tiered access
- Anti-trust
- Liability
- Logistics and operations
- Infrastructures
- Quality control

Do we understand (and can we begin to measure) the benefits that accrue from KMs?

Experts at the Workshop identified a number of benefits which accrue from participation in Knowledge Markets including for:

a) Scientific advance

- Interdisciplinary collaboration, silo break down: bring new approaches, disciplines and modes of work to bear on particular problems
- Tap into broader, global research community
- Data mining
- Close loop between clinicians and researchers

b) Knowledge management

- Increases collaboration between parties – especially needed to tackle new diseases and treatment paradigms
- Facilitates incremental (and distributed/networked/hived) innovation
- Increases the flow of information (access, flow, management)
- Formalises rules of engagement
- Creates trust
- Creates feedback loops of information with users and clinicians (regarding needs, evaluation)
- Allows learning about *how* to bring research to market more efficiently

c) Public health benefits

- Increases evidence-based treatment options (predicting therapeutic response population)
- Improves transparency of health information
- Accelerates shift to personalised medicine
- Encourages early adoption of treatments
- Catalyses investment in identified public health need

d) Regulatory – Industry dialogue:

- Tackles challenge of personalised meds and targeted therapies (*i.e.*, how they will be developed and delivered)
- Improves biomarker validation and paves way for regulatory acceptance
- Tackles next generation clinical trial design

- Creates safe haven for new approaches to knowledge sharing and risk sharing (if anti-trust issues are addressed)
- Help establish stable, predictable, transparent regulatory pathways

- There is a good deal of work to be done, however, to document that such benefits actually do accrue. Moreover, there may need to be work on measures of success for individual knowledge markets and on where and how Knowledge Markets work well.

The government policy interest in KMs

Numerous different reasons for government interest in Knowledge Markets emerged from workshop discussions ranging related to health policy, research policy, industrial policy, and intellectual property rights policy. These included mention of the need to:

- Push biomedical research into 21st Century – toward a more evidence and data based, predictive science
- Ensure research infrastructure development and sustainability
- Disseminate publicly funded research results
- Improve technology transfer
- Plug into international research networks
- Biomedical cluster/industrial policy
- Define acceptable patenting/licensing behaviour of public sector research organisation
- Address health care product productivity slump
- Reduce attrition rates especially in late stage research
- Meet health care needs of population and improve outcomes
- Boost delivery and access to new health products
- Reduce health care costs
- Improve consumer information and health care choice

Impacts on industry and business models for health delivery – where do KMs take us?

- Capitalism is based on an extensive division of labour and increasingly specialized, complex industry organisation. However, there is a sense that the division of labour, and the hand-off of knowledge intensive goods and services between the different actors in the value chain, is not working well in the health biotechnology and pharmaceutical sector.
- While there is uncertainty and disagreement about what the ideal industry structure to foster biomedical innovation might be, there is strong evidence that partnerships and networking help address need for risk reduction and cost sharing.

1. Do Knowledge Markets enable new business models to develop?

- Knowledge markets do enable experimentation with new business models and there are numerous examples to date of what these models include.
  - Innocentive, which provides a model of "hive" pharmaceutical development

- Increased pharmaceutical firm outsourcing of knowledge through virtual networks
- New approaches to clinical trial design and regulatory approvals which could:
    - Facilitate the emergence of personalised meds
    - Service small markets (orphan drugs, neglected diseases)

- There was some concern, however, that a proliferation of Knowledge Markets might not simply increase the flow of knowledge amongst actors but perversely make co-ordination amongst such groupings more complicated.

2. *Does financial pressure for better valuation impact knowledge management strategies?*

- Intellectual Asset reporting is in its infancy, in the long term it could help innovative firms distinguish themselves as good investment opportunities and thus capture more capital.
- In the short term, voluntary intellectual asset reporting helps management understand its own intellectual asset strengths and communicate those externally.
- Investors - both VCs and institutional investors -- do not consider long term pay offs from intellectual assets, as their time horizon are short in comparison with the business cycle of the biopharma sector. Moreover, most investors take a portfolio approach which mitigates the need to collect individual data.
- Financial pressures do not yet play a major role in firm decisions to enter into KMs.
- Securitised portfolios of leads or clinical trials offer another potential source of capital for biomedical firms. In this model a large number of (projects)/(firms) are bundled together into a portfolio which investors inject a one-off large capital investment in exchange for guaranteed income over course of a long time period.

3. *What elements might encourage a greater use of Knowledge Markets?*

- For knowledge markets to become more common than now the case, new infrastructures will likely need to be put in place.
- Part of the solution will be information technology and software based. Inter-organisational information systems – or electronic marketplaces - allow buyers and sellers to exchange information about prices and product offerings. For this to happen, advances are still needed in order to be able to represent knowledge objects in electronic market places so that they can be brokered and traded.
- Improved methodologies for the valuation of knowledge intensive intellectual assets – or knowledge objects – would also facilitate the emergence of knowledge markets. Brokerages, prizes and firms that provide outsourced knowledge intensive products and services already exist. They help put a value to knowledge intensive intellectual assets. It is quite possible these sorts of business models will become more common.
- Still in development are the idea of warehouses or safe brokerage services which act as intermediaries between buyers and sellers. Their function would be to be a trusted broker that maintains the confidentiality of their clients' knowledge intensive assets while providing enough information to potential buyers so as to price and trade the assets. Such services would independently value knowledge intensive assets, help potential sellers evaluate the opportunity costs of keeping a knowledge intensive asset in house, and make available select information about these assets to potential buyers so that they can be traded.