What do patent-based measures tell us about product commercialization?

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PDSM 2013

12 November 2013

We find that relationship between patent-based measures and product development outcomes is more nuanced than suggested by prior literature

INTRODUCTION

- Patent-based measures are widely used by researchers in economics and management to characterize inventions and research capabilities more broadly
- Series of papers has established strong correlation between value of invention and # citations received (Trajtenberg, 1990; Harhoff et al., 1999; Gambardella, Harhoff & Verspagen, 2008)
- Increasingly used to proxy for outcomes beyond simple value with much less support
- Using data from the pharmaceutical industry, we examine relationship between patent-based measures and how fast and how far the underlying product proceeds through the product development process
- We find a nuanced relationship between the patent-based measures and the product development outcomes

Patent-based measures often used as a proxy for innovative output, but – other than citations for patent value – measures have not been validated

REVIEW OF PRIOR LITERATURE

- Early work employing patent data mainly used patent counts as a measure of innovation output (see Griliches, 1990)
- More recent work has constructed more refined indicators from information contained in patent documents
  - Value of invention using # citations a focal patent receives (Trajtenberg 1990, Harhoff, Scherer & Vopel, 1999), patent renewals (Pakes & Schankerman, 1984; Pakes, 1986; Schankerman & Pakes, 1986; Lanjouw, Pakes & Putnam, 1998), patenting countries (Putnam, 1996), and opposition (Harhoff, Scherer & Vopel, 2003)
  - Nature of inventions using distribution of technology classes (Henderson, Jaffe & Trajtenberg, 1998), patent vs. non-patent references (Trajtenberg, Henderson & Jaffe, 1997), non-patent references (Narin & Noma, 1985)
  - Technological overlap (Jaffe, 1986; Mowery, Oxley & Silverman, 1996) and fragmentation of ownership (Ziedonis, 2004)
  - Weaknesses in patents/portfolios using EPO's "X" and "Y" classification of references (Michel & Bettels 2001; Webb et al. 2005; Grimpe & Hussinger, 2008; Czarnitzki, Hussinger & Leten, 2011; Guellec, Martinez & Zuniga, 2012) and existence of patent thickets (von Graevenitz, Wagner, and Harhoff, 2011)
- Research has established a clear correlation between value of an invention and # citations received (Trajtenberg, 1990; Harhoff et al., 1999; Gambardella, Harhoff & Verspagen, 2008)
- Other indicators either have not been validated or validation relies on outcomes internal to patent system
  - e.g., relationship between X/Y references & patent grant (Harhoff & Wagner, 2009) and patent opposition (Harhoff & Reitzig, 2004)

Patent-based measures reflect patentability and technological value but not necessarily product development outcomes

RESEARCH QUESTION

- Patent-based measures may reflect patentability and/or technological value (e.g., novelty) but product development also depends on commercial “feasibility” and impact
- Although citations correlated with value, they only explain a small proportion (Gambardella, Harhoff & Verspagen, 2008)
- Correlation between patent counts and product introductions is weak, even in pharmaceutical industry (Graham & Higgins, 2007)

What do patent-based measures tell us about product development outcomes (beyond patentability and technological value)?

To explore this question we combine information on the product-development history of pharmaceutical products with patent data

EMPIRICAL SETTING & DATA SOURCES

- We study the relationship between patent-based measures and commercialization of pharmaceutical products
  - "Discrete" nature of technology creates clear link between (a few) patents and the products they cover
  - IP rights tend to be "strong" and important (Cohen, Nelson, & Walsh, 2000)

- Use IMS R&D Focus database, matching pharmaceutical products to primary patents covering those products
  - Contains development/commercialization history of all projects (approx. 30000) known to be in development from 1980s to present (including projects that failed in clinical trials)
  - Provides patent information on primary patents covering the product for approx. 30% of those products

- Use PATSTAT to match primary patents listed in IMS R&D Focus to European patent equivalents
  - Identify 5,923 products covered by 8248 unique EP patents

We construct a range of patent-based measures from information on EP equivalent of primary patent(s) covering pharmaceutical product

DESCRIPTION OF PATENT-BASED MEASURES

Legal status of the patent application	• Whether patent granted • Whether granted patent challenged in an opposition • Whether opposed patent upheld after opposition
Procedural information & characteristics of the patent document	• # patents belonging to patent family (family size) • Whether filed under the Patent Cooperation Treaty (PCT) • # claims included in paten filing • 2-digit IPC classification (IPC2)
Citation-based measures	• # citations received within 5 years (forward cites) • Share of citations from X/Y patent references • Generality
Reference-based measures	• # patent references • # non-patent references • Share of X/Y-type references • Originality
Applicant characteristics	• Cumulated # applications • (1) government/non-profit; (2) university/hospital; (3) individual • Whether applicant is from US/Japan/ROW

Patent-based measures for patents in dataset are strongly correlated with patenting outcomes & more correlated than other patents in same application year and IPC class

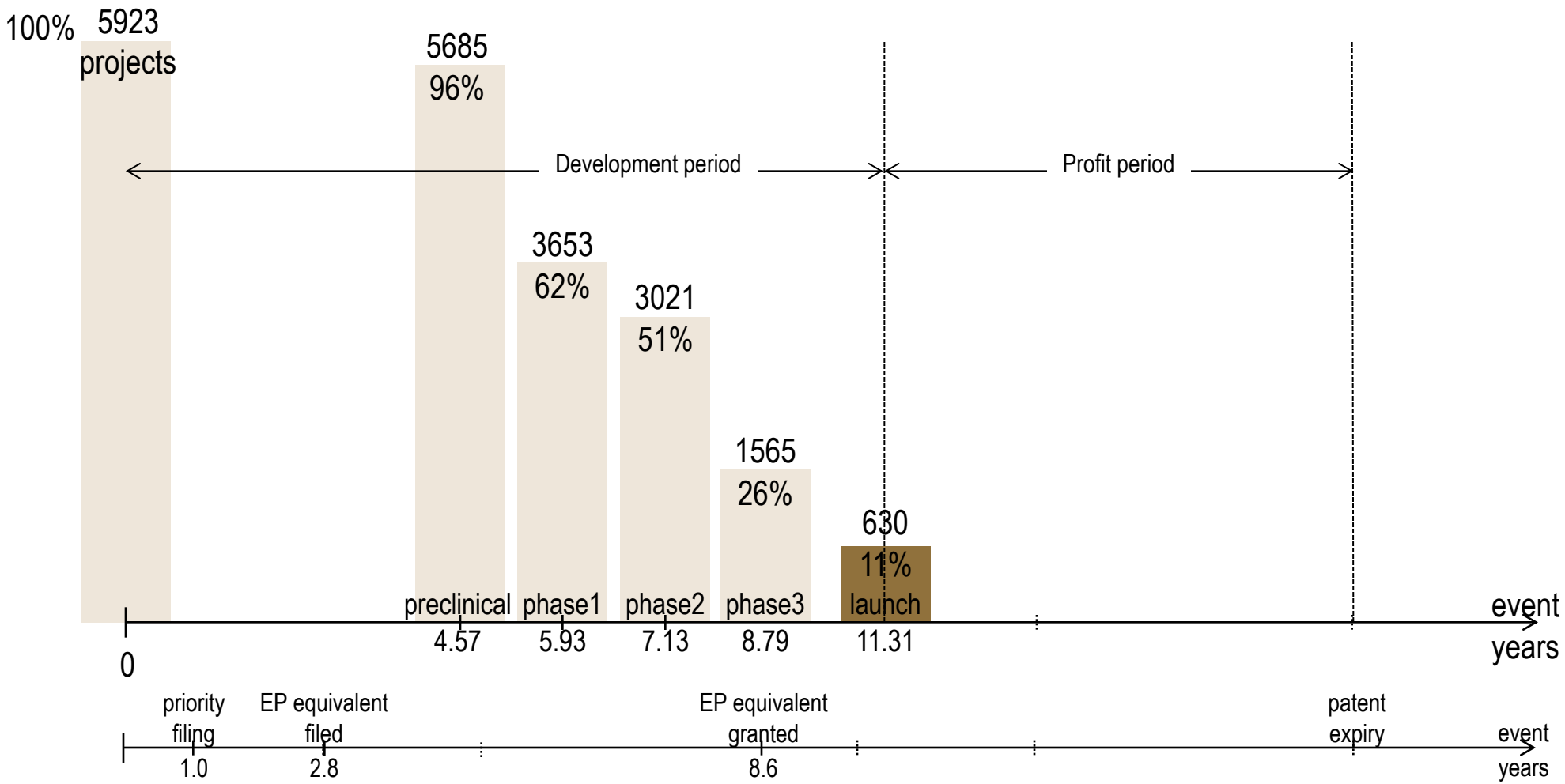
MEAN VALUES OF PATENT-BASED MEASURES BY PATENTING OUTCOMES

		Legal status of the application			
		Granted		Opposed	
	All	No	Yes	No	Yes
Observations	8248	2601	5647	5280	367
Share of all patents	100.0%	31.5%	68.5%	93.5%	6.5%
	100%	47.3%**	52.7%**	93.8%	6.2%
Procedural information					
Filed under PCT	56.7%	61.2%	54.6%	53.8%	65.9%
	51.7%**	56.0%**	47.8%**	47.8%**	48.1%**
Family size	15.6	9.7	18.3	18.1	21.4
	9.87**	7.16**	12.11**	11.97**	14.26**
# Claims	21.2	24.2	19.8	19.4	25.0
	16.76**	18.04**	15.60**	15.44**	18.08**
Citation-based measures					
# Forward cites	1.87	1.50	2.04	1.93	3.53
	1.13**	1.04**	1.22**	1.16**	2.08**
Generality	0.21	0.15	0.24	0.24	0.25
	0.13**	0.11**	0.15**	0.15**	0.19**
Reference-based measures					
# Backward refs	3.21	3.64	3.01	3.03	2.83
	3.21	3.35**	3.08*	3.06	3.48**
X refs % of refs	27.0%	34.7%	23.5%	23.3%	26.8%
	34.5%**	39.5%**	29.6%**	29.0%**	36.9%**
Y refs % of refs	11.0%	12.1%	10.5%	10.4%	11.5%
	14.9%**	15.5%**	14.3%**	14.4%**	14.1%**
Originality	0.41	0.41	0.41	0.40	0.50
	0.38**	0.39**	0.36**	0.36**	0.38**

*Product patents in light shade; similar patents in dark shade; diff: * p<0.10, ** p<0.05, *** p<0.01*

Pharmaceutical products suffer severe attrition as they progress through clinical trials, and high level of survival in pre-clinical trials in dataset reflects data sources

TIMELINE OF KEY PRODUCT DEVELOPMENT & PATENTING EVENTS



Family size and forward citations higher at later stages of product development process, but probability had PCT filing, backward references, and share of X references lower

MEAN VALUES OF PATENT-BASED MEASURES BY STAGE REACHED

	Total	preclinical	phase 1	phase 3	launched (any EP)
Observations	5923	5685	3653	1565	630
Share	100.0%	96.0%	61.7%	26.4%	10.6%
Procedural information					
Filed under PCT	58.2%	57.3%	54.4%	48.5%	41.1%
Family size	16.01	16.19	17.99	19.07	22.19
Citation-based measures					
# Forward cites	1.97	1.95	1.99	2.03	2.35
Reference-based measures					
# Backward refs	3.22	3.21	3.16	3.03	2.83
X refs (% of refs)	25.6%	25.38%	25.32%	24.44%	21.56%
Y refs (% of refs)	11.3%	11.2%	11.5%	13.3%	12.5%

We use both hazard-rate analysis to model relationship between patent-based measures and outcomes

EMPIRICAL SPECIFICATION

- Probit models show whether change in patent-based measure was correlated with an outcome

- BUT only know patenting outcomes up to end of 2011 and product commercialization outcomes up to the end of 2009
  $\Rightarrow$ we may not observe ultimate outcomes for more recently developed patents

- Use Cox proportional hazard-rate model of product launch to account for truncation/censoring

  $$h(Y \mid t, X) = h(Y \mid t)\exp(X\beta)$$

  where Y is indicator of whether product was launched

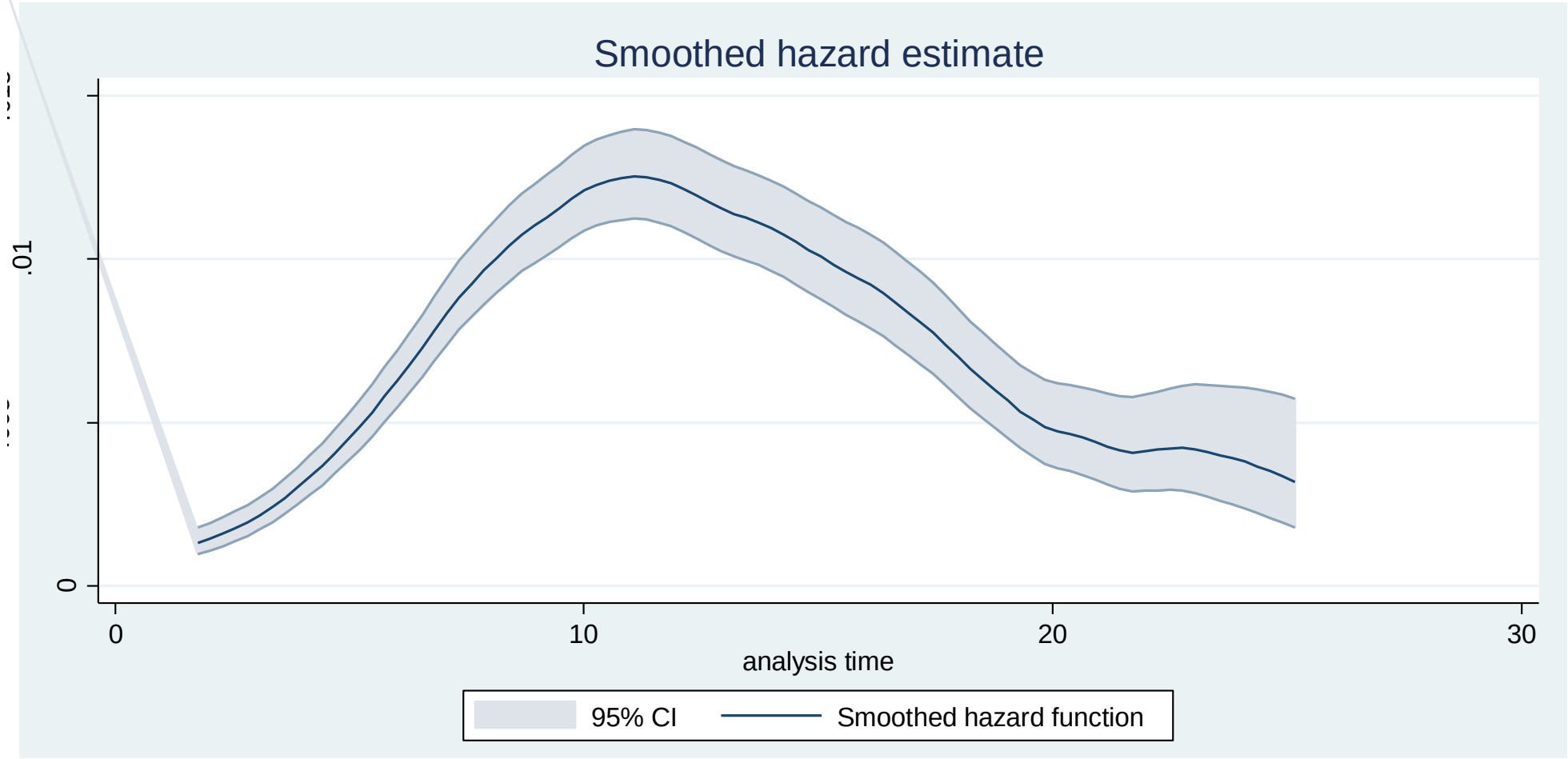
  t is time since product invention (in years)

  X is a vector of explanatory variables

- With multiple patents per product we weight observations by inverse of patents per product so all products are weighted equally

Hazard-rate analysis compares outcomes of products of similar age

SMOOTHED HAZARD OF PRODUCT LAUNCH CONDITIONAL ON TIME SINCE INVENTION



Results from regressions on patenting outcomes largely replicate results from the prior literature

RELATIONSHIP BETWEEN PATENT-BASED MEASURES AND PATENTING OUTCOMES

	Patent grant		*Opposition*
	Probit (MFX)	*Cox (haz. rates)*	*Probit (MFX)*
Patent characteristics			
Filed under PCT	0.118***	1.221***	0.029***
	(8.15)	(5.50)	(3.78)
Family size	0.018***	1.029***	0.001***
	(30.24)	(27.72)	(4.79)
# Claims	-0.001***	0.994***	0.000***
	(-4.75)	(-6.81)	(2.77)
Citation-based measures			
# cites within 5 years (log)	-0.011	0.950***	0.024***
	(-1.08)	(-2.17)	(5.57)
Generality	0.160***	1.762***	-0.035***
	(5.75)	(8.38)	(-2.60)
Reference-based measures			
Share of X references	-0.084***	0.743***	0.020***
	(-4.96)	(-6.74)	(2.28)
Share of Y references	-0.043*	0.862***	0.016
	(-1.86)	(-2.53)	(1.36)
Originality	-0.125***	0.664***	0.031***
	(-7.24)	(-9.68)	(3.62)
Appl. char., IPC & year dummies	YES	YES	YES
Observations	8248	8248	5618

** p<0.10, ** p<0.05, *** p<0.01; t-statistics in parentheses*

- Results on likelihood of patent grant largely consistent with Harhoff & Wagner (2009)
  - increases with PCT filing, family size & generality
  - decreases with # claims, # forward citations, total # references and share of X/Y-type references & originality
- Results on opposition consistent with Harhoff & Reitzig (2004) & Harhoff, von Graevenitz & Wagner (2012)
  - increases with PCT filing, family size, # claims, # forward citations, X-type references and originality
  - decreases with generality

Patent-based measures have nuanced relationship with product development outcomes

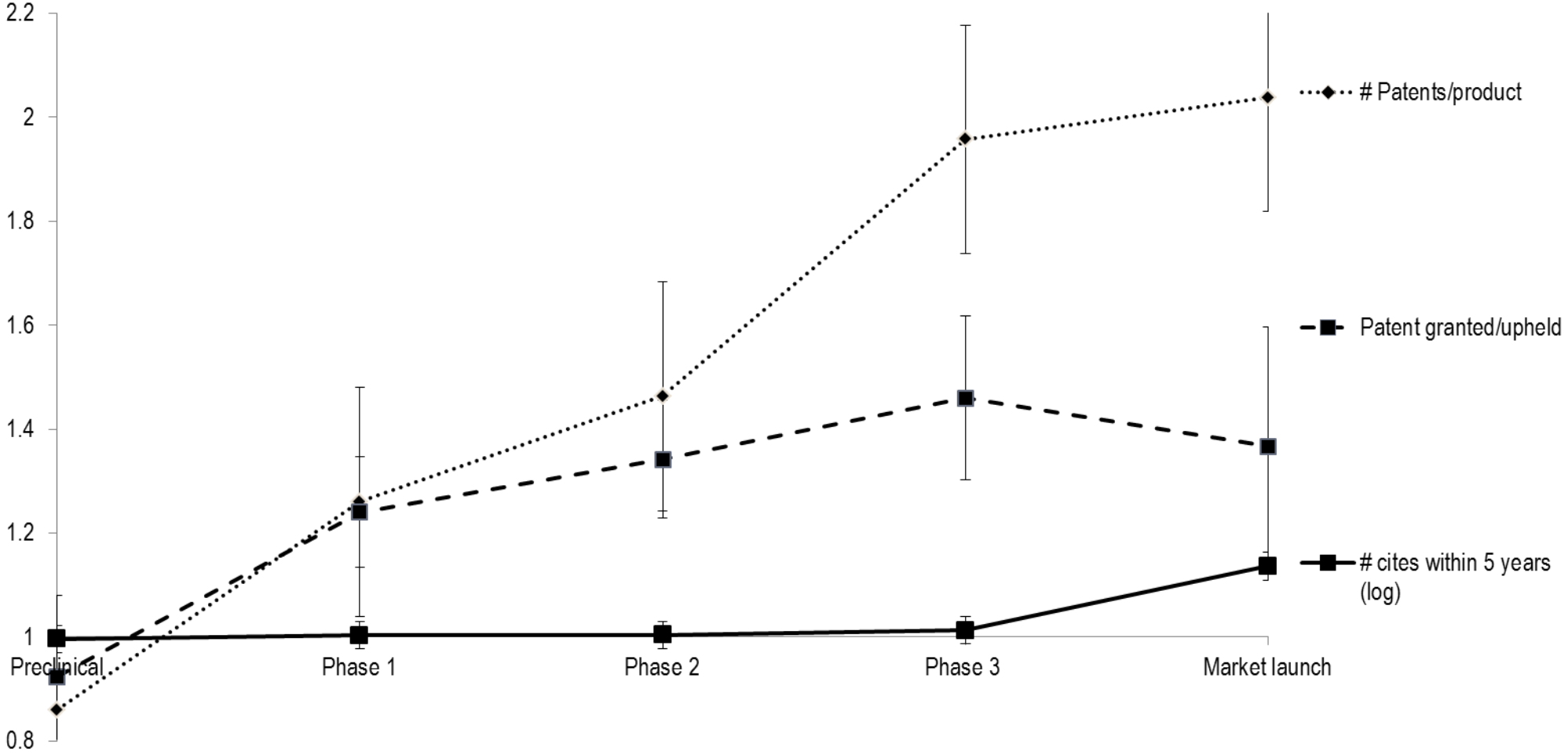
RELATIONSHIP BETWEEN PATENT-BASED MEASURES AND HAZARD OF DEVELOPMENT OUTCOMES

Stage product reached	*Preclinical*	*Phase 1*	*Phase 2*	*Phase 3*	*Market*
Patent characteristics					
Patent granted/upheld after opposition	0.924***	1.240***	1.342***	1.460***	1.367***
	(2.47)	(4.43)	(5.90)	(5.70)	(3.13)
# patents/product	0.860***	1.260***	1.463***	1.958***	2.038***
	(6.16)	(7.43)	(13.20)	(18.92)	(14.33)
Filed under PCT	0.972	0.915***	0.926	0.922	0.831***
	(0.84)	(1.69)	(1.47)	(1.09)	(1.72)
Family size	0.999	1.027***	1.031***	1.034***	1.044***
	(1.05)	(15.52)	(18.01)	(14.27)	(14.36)
# Claims	0.999	1.003***	1.002***	1.002	1.003
	(0.73)	(2.40)	(2.24)	(1.01)	(1.35)
Citation-based measures					
# cites within 5 years (log)	0.996	1.003	1.004	1.013	1.136***
	(0.20)	(0.11)	(0.12)	(0.32)	(2.10)
Generality	1.200***	1.436***	1.377***	0.931	0.653***
	(3.02)	(4.05)	(3.62)	(0.58)	(2.29)
Reference-based measures					
Share of X references	0.910***	1.107***	1.218***	1.232***	1.148
	(2.44)	(1.76)	(3.41)	(2.74)	(1.18)
Originality	1.003	1.072	1.078	1.139***	1.109
	(0.07)	(1.24)	(1.36)	(1.75)	(0.94)
Applicant characteristics, IPC2 & year dummies	YES	YES	YES	YES	YES
Observations	9217	9176	9197	9192	9229

*Cox hazard rates; * p<0.10, ** p<0.05, *** p<0.01; t-statistics in parentheses*

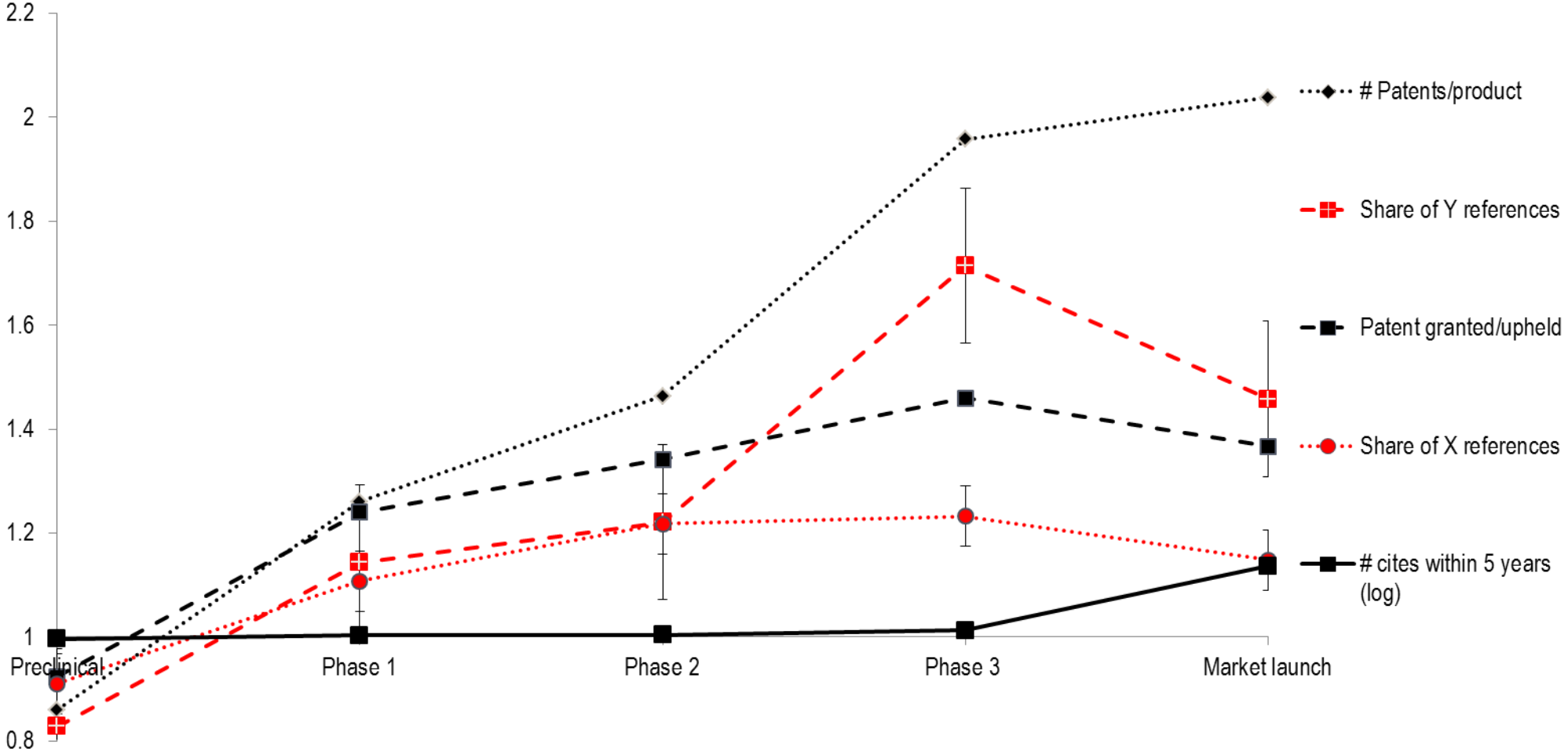
Patent-based measures of both "value" and "risk" are negatively correlated with entering preclinical trials but positively (and increasing) with product development outcomes

RELATIONSHIP BETWEEN "VALUE" & "RISK" MEASURES AND HAZARD OF DEVELOPMENT OUTCOMES



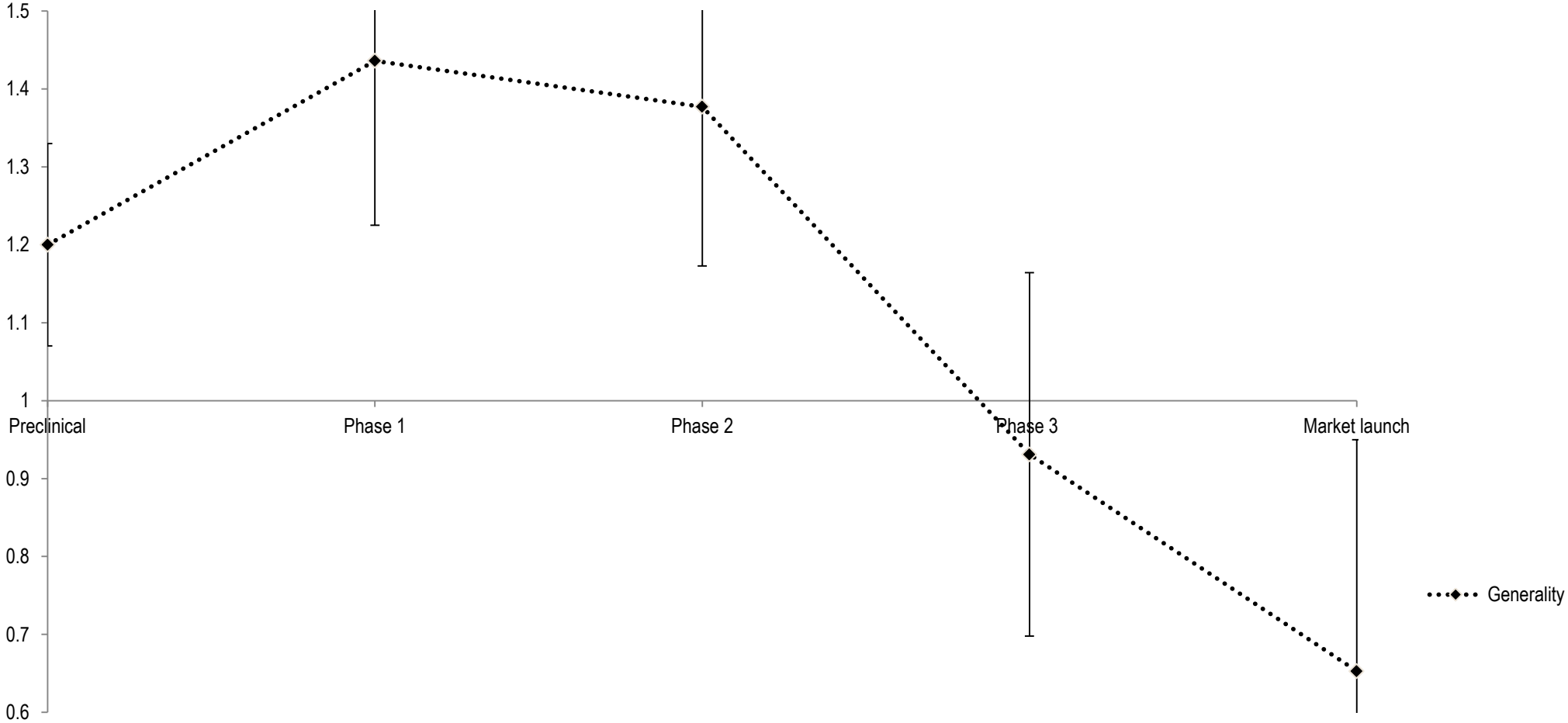
Patent-based measures of both “value” and “risk” are negatively correlated with entering preclinical trials but positively (and increasing) with product development outcomes

RELATIONSHIP BETWEEN “VALUE” & “RISK” MEASURES AND HAZARD OF DEVELOPMENT OUTCOMES



Higher generality positively correlated with entering early-stage trials but negatively correlated with product launch, while originality not correlated with product development

RELATIONSHIP BETWEEN GENERALITY & ORIGINALITY AND HAZARD OF DEVELOPMENT OUTCOMES



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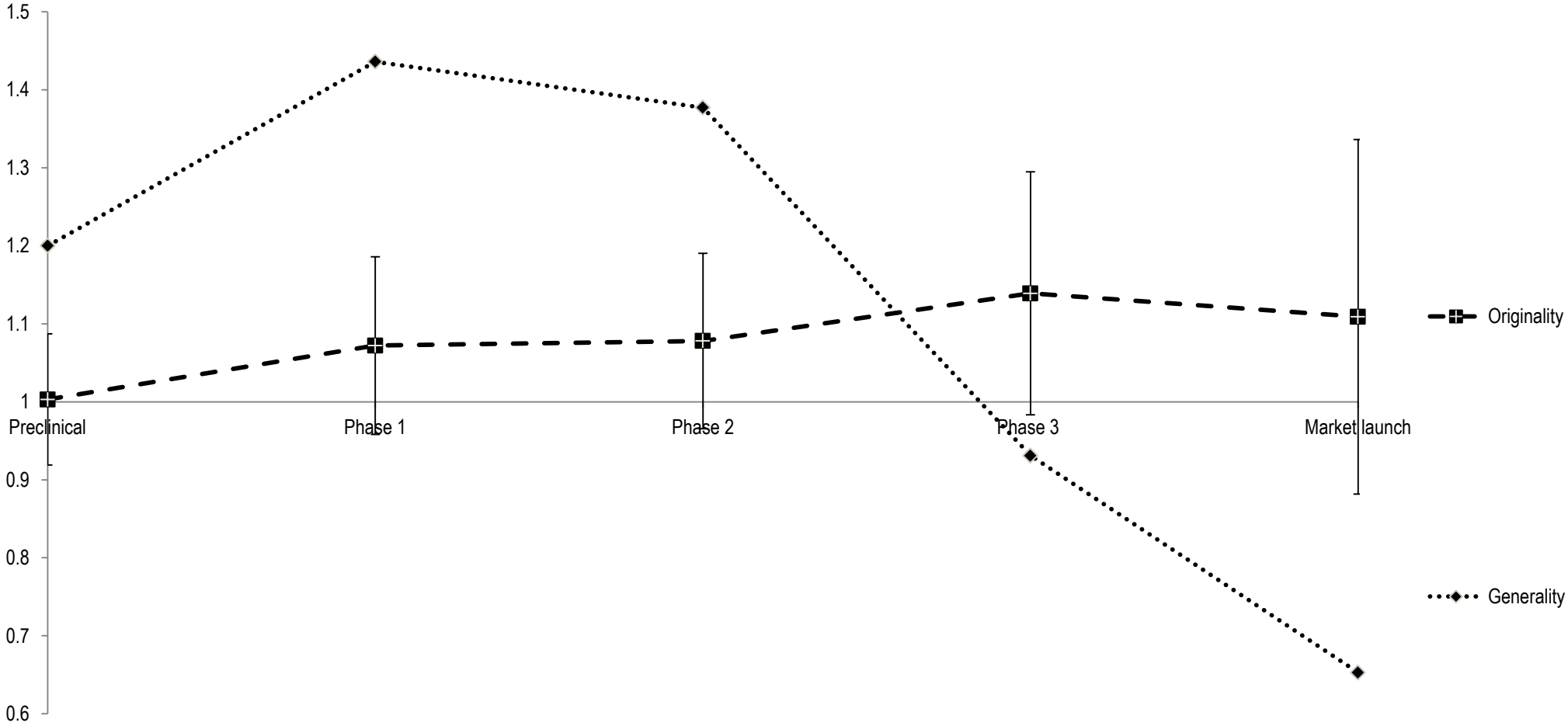
RELATIONSHIP BETWEEN GENERALITY & ORIGINALITY AND HAZARD OF DEVELOPMENT OUTCOMES



We see similar (and often stronger) relationships between patent-based measures and whether/how fast a product progresses to next stage

RELATIONSHIP BETWEEN PATENT-BASED MEASURES AND DEVELOPMENT PROGRESSION

Time from	*Invention to Preclinical*	*Preclinical to Phase 1*	*Phase 1 to Phase 2*	*Phase 2 to Phase 3*	*Phase 3 to Approval*	*Approval to Launch*
Patent characteristics						
Patent granted/upheld after opposition	0.924***	1.282***	1.337***	1.487***	1.405***	1.304***
	(2.47)	(4.38)	(4.93)	(5.57)	(4.19)	(2.52)
# Patents/product	0.860***	1.358***	1.625***	2.189***	2.334***	2.304***
	(6.16)	(7.67)	(12.67)	(19.84)	(18.66)	(15.57)
Filed under PCT	0.972	0.942	0.905	0.827***	0.924	0.844
	(0.84)	(0.93)	(1.53)	(2.32)	(0.82)	(1.48)
Family size	0.999	1.016***	1.026***	1.036***	1.041***	1.048***
	(1.05)	(7.36)	(12.95)	(14.46)	(14.56)	(14.78)
# Claims	0.999	1.004***	1.003***	1.003***	1.003	1.001
	(0.73)	(3.81)	(2.42)	(2.01)	(1.63)	(0.40)
Citation-based measures						
# cites within 5 years (log)	0.996	0.995	0.983	0.999	0.965	1.116**
	(0.20)	(0.14)	(0.43)	(0.01)	(0.67)	(1.68)
Generality	1.200***	1.523***	1.815***	1.508***	1.035	0.773
	(3.02)	(3.86)	(5.46)	(3.13)	(0.23)	(1.31)
Reference-based measures						
Share of X references	0.910***	1.129**	1.082	1.260***	1.318***	1.262**
	(2.44)	(1.72)	(1.11)	(2.73)	(2.90)	(1.94)
Originality	1.003	1.165***	1.121**	1.164**	1.125	1.027
	(0.07)	(2.18)	(1.65)	(1.85)	(1.25)	(0.23)
Applicant characteristics, IPC2 & year dummies	YES	YES	YES	YES	YES	YES
Observations	9217	9150	8770	9084	9084	9114

*Cox hazard ratios; * p<0.10, ** p<0.05, *** p<0.01; t-statistics in parentheses*

We now seek to understand the complicated relationship between patent-based measures and product-development outcomes

CONCLUSION

- Two main findings:
  - Relationship between patent-based measures and patenting outcomes for product-related patents is consistent with prior literature
  - Relationship between patent-based measures and product-development outcomes is more complicated
    - Both “value” and “risk” measures negatively correlated with early-stage development but positively correlated with later-stage development
    - Generality positively correlated with early-stage development but negatively correlated with later-stage development

- Potential explanations:
  - For products with higher risk/higher reward, firms delay clinical development before resolving patenting uncertainty
    - BUT including patent status as covariate (time-varying or not) does not appear to affect results
  - Products protected by more general (GPT) patents more likely to be advanced at earlier stage but encounter difficulty at later stages

- We plan to investigate the explanations for these findings more fully in future work