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# 508 Conceptualizing market formation for transformative 509 policy

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#### 520 Abstract

521 Transitions are hardly conceivable without understanding how new markets are formed. However, there is still an incipient conceptualization of market formation in the context of transformation and 522 transformative policy. Drawing on existing perspectives of market formation in the literature, this paper 523 develops a framework for characterizing, differentiating and analyzing new market formation processes. 524 We use three case studies to demonstrate how the framework is able to capture the dynamic and 525 interconnected nature of market formation. The market formation framework serves to diagnose 526 potential misalignments, bottlenecks and failures, to identify entry points for policy to intervene in 527 market formation and support transformative innovation. 528

529 **Keywords:** market formation; transitions; policy entry points; transformative innovation policy.

530

#### 531 **1. Introduction**

Addressing grand societal challenges and the Sustainable Development Goals requires transitions to 532 new kinds of socio-technical systems and has led to calls for transformative innovation policy (Borrás 533 & Edler, 2020; Diercks et al., 2019; Köhler et al., 2019; Schot & Steinmueller, 2018). Transitions 534 535 involve radical innovations, systemic socio-technical changes and extensive restructuring of economies. As a focal point for these dynamics, markets have been recognized as essential mechanisms for 536 inspiring, upscaling and generalizing innovative solutions (Robinson & Mazzucato, 2019). Therefore, 537 it stands to reason that many activities associated with transitions eventually lead to changes to existing 538 markets and inspire the formation of new ones. 539

Transition studies have recognized market formation as an essential dimension (Bergek et al., 2008;
Hekkert et al., 2007). Markets are commonly defined as arenas or structures that allow for and organize
the exchange of products or services between sellers and buyers (Fligstein & Dauter, 2007). Market
formation involves processes leading to new arenas for the exchange of products or services throughout
an innovation's journey (Rip, 2012; Van de Ven, 1999).

However, how markets are formed in transitions have for long been subjected to rather cursory 545 treatment. First, market formation is often studied in terms of which user groups to target and how to 546 improve innovation adoption, in essence taking a diffusion perspective (Boon et al., 2020; Loorbach et 547 al., 2020; Rogers, 2003). Such a diffusion perspective treats upscaling as an inevitable, linear process. 548 549 Relatedly, innovation systemic approaches to transformative change have shown a failure in anticipating 550 and learning about user needs. Weber and Rohracher (2012) called this a demand articulation failure 551 and saw a necessity to take user needs and practices into account. Second, transition frameworks like 552 the technological innovation system (TIS) framework apply market formation largely as a black box. 553 Recent studies, like Bergek et al. (2015) demonstrate that market formation policies need to be understood in the context of the underlying structures and processes of legitimization with which the 554 555 policy interferes. While highly insightful and important, such case studies, however, do show that there is the need to a more systematic and differentiated conceptualization of the market formation phase. 556

557 Only recently, more attention has been paid to the process dimension of market formation (Dewald & Truffer, 2012; Hyysalo et al., 2018), and the complexities and uncertainties associated with market 558 formation that involve a wide variety of institutions and stakeholders, like firms, customers, community 559 organizations and governments (Fligstein & Dauter, 2007; Schanz et al., 2019; Vargo et al., 2017). Over 560 the last decade, efforts have been made to elaborate on end-user markets by emphasizing supporting 561 562 narratives and their institutional contexts (Dewald & Truffer, 2011, 2012; Ottosson et al., 2020), as well as the fact that the emergence of markets interacts with other systemic processes such as gaining 563 legitimacy and producing knowledge for technologies (Binz & Truffer, 2017). 564

With this article we want to advance and explicate this work on market formation to make it relevant 565 for and to support policymaking in the context of transitions. There is a need to disentangle the processes 566 comprising market formation in order to identify misalignments, bottlenecks and failures for which 567 policy interventions can then be devised. Similar to how the 'functions' capture the core processes that 568 enable technological innovation systems to emerge (Bergek et al., 2008; Hekkert et al., 2007), we aim 569 570 to unpack the black box of market formation by differentiating five major processes of market formation. The aim of this paper is therefore to develop a multidimensional framework for characterizing and 571 analyzing different processes of new market formation in the context of transformative innovation 572 573 policy.

574 For transformative policy, while there are a wide variety of innovation types and sources that may contribute to solving grand societal challenges, new technological innovations hold great promise to 575 576 contribute to the desired systemic and transformative changes. Recognizing the wide variety of possible 577 forms of market formation, we made a deliberate choice to focus on technology-based market formation 578 when developing our framework. We chose to focus on emerging markets that are inspired by new (applications of) technologies despite being aware of the relevant nuances related to venturing into new 579 580 sectoral, demographical or geographical contexts. We did so because technological solutions often promise to shape and drive future transitions, as they have in the past (Geels, 2002). Further, we see this 581 582 focus on technological innovations as a first step towards a broader understanding of market formation which would have to include new business models and social innovations that support transformations 583 584 once scaled up.

585 Our main aim is to advance the literature on transformative innovation policy by identifying potential 586 misalignments, bottlenecks and (market and systemic) failures during early stages of technology 587 emergence. They serve as entry points for incipient market formation policies. Particularly in times 588 when the state is called upon to support and accelerate transformations, it is of paramount importance 589 to have a thorough understanding of market formation processes and their deficiencies. Understanding

the emergence of markets inevitably must be a concern for governments as they are interested in solving 590 societal problems and are able to regulate or push market creating processes that the interplay of private 591 actors alone cannot advance. So, we want to advance thinking about markets and already start 592 considering markets in the emergence phase of technologies. We also complement and contribute to the 593 594 transition studies by emphasizing the demand side in e.g. technological innovation systems (Bergek et 595 al., 2015) and sectoral policies needed for enabling the interplay between and synchronization of 596 emerging markets, e.g. mobility-as-a-service, the sharing economy and the circular economy. Finally, 597 our framework may also be of interest to organization and marketing studies, as these have recently addressed the role of so-called 'moral markets' in dealing with societal challenges and wicked problems 598 (Georgallis & Lee, 2020; Nenonen et al., 2021) and the understudied role of technology as a basis for 599 600 shaping markets (Kaartemo & Nyström, 2021).

601 We develop our framework drawing on the various streams of literature which provide diverse and 602 complementary insights into the market formation process from different theoretical perspectives 603 (Section 2). In Section 3, we outline the conceptual framework comprising five major market formation processes and describe its stepwise development. We then demonstrate how the framework can act as 604 an advanced diagnostic tool that provides useful insights into market formation processes using three 605 illustrative cases (Section 4). We close the paper by, first, reflecting on the ramifications of our findings 606 607 for transformative innovation policy that seeks to support market formation in the context of politically and societally desired transformations, and, second, outlining next steps to test and further develop our 608 framework for analyzing new market formation processes (Section 5). 609

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#### 2. Existing perspectives of market formation

The framework we aim to develop needs to refine how transition studies deal with market formation. 612 613 Our refinement was inspired by three bodies of literature that provide important foundations for transition studies (Geels, 2002): the evolutionary economics of innovation, the sociology of markets 614 and, to a lesser extent, marketing studies. These are recognized as the main literatures that study the 615 creation and evolution of markets (see Diaz Riuz, 2012 for a review). It becomes clear that divergence 616 and crosspollination have occurred in the way these literatures perceive markets. For example, both the 617 618 sociology of markets and marketing studies build on the same sources and notions in relation to markets 619 as narratives (Sprong et al., 2021). In the final subsection, we examine how markets have so far been incorporated into transition studies. As will become clear, these bodies of literature are complementary: 620 they have all become interested in endogenizing market formation and recognizing similar (material, 621 cognitive, institutional) dimensions. When presenting each body of literature, we number the main 622 concepts adopted from it and used to build our set of market formation processes in the next section (see 623 numbering in Figure 1 below). 624

#### 625 2.1 Evolutionary economics, innovation and markets

To explain how innovations come about, evolutionary economics has gone beyond perceiving markets 626 as trade arenas in which buyers and sellers with rational preferences and full information maximize 627 utility and profits. Product innovation is regarded as the result of interactive learning between users and 628 629 producers, who exchange knowledge about needs and use values in so-called 'organized markets' 630 (Lundvall, 1988). Markets are regarded as complex and dynamic systems in which knowledge about innovations is created, adopted and retained, and therefore as selection environments for innovations 631 (Bleda & Del Río, 2013; Nelson & Winter, 1977). 632

Originally, evolutionary economics took markets for granted (Murmann & Frenken, 2006). The introduction of innovations was associated with a variety of technological options, latent demand and many suppliers. Firms sell their variant in associated niche markets, addressing a specific subset of customer segments (Sarasvathy & Dew, 2005) and avoiding direct competition with incumbent firms (Malerba et al., 2007). Subsequently, product characteristics become established in the form of a 'dominant design' (Clark, 1985; Suárez & Utterback, 1995), which also leads to homogenized customer segments (Adner & Levinthal, 2001).

Evolutionary economics then evolved and increasingly considered the demand side and interactions with 640 users. A critical level of consensus is required about how the product should be used and which 641 preferences are met (Benner & Tripsas, 2012). Tripsas (2008) underlines consumers' uncertain and 642 643 unarticulated preferences vis-à-vis innovations, and *preference formation and demand articulation* (1) 644 due to, e.g. new regulations and changing consumer needs. Suarez (2015) extends this cognitive 645 dimension of markets by introducing so-called *dominant product categories* (2) that precede the emergence of a dominant design (3). Such dominant product categories include "the attributes, benefits, 646 and usage conditions with which products must comply to be considered members in good standing" 647 (Rosa et al., 1999) and draw cognitive boundaries around product markets. 648

## 649 **2.2 Marketing studies**

Traditionally, marketing scholars perceived markets as pre-existing spaces in which individual firms launch their products. They target consumers with differing preferences and degrees of eagerness to embrace novelty (Rogers, 2003). Firms aim to structure consumer demand through *customer segmentation* and induce preferences through *marketing activities* (4).

654 Recent marketing studies have explicitly moved away from the notion of markets as pre-existing exchange modes or customer segments with fixed preferences (Kindström et al., 2018). They emphasize 655 656 the endogenous and open-ended nature of markets (Kjellberg et al., 2015) and view market creation as ongoing processes that actors can influence (Nenonen et al., 2019). Preferences are not static and are 657 formed by demand articulation (1). Demand uncertainty decreases as product categories become 658 coherent and legitimate and companies or governments can educate consumers about a product's 659 meaning and use (Doganova & Karnøe, 2015). Moreover, markets are regarded as co-evolving with 660 institutions: institutional entrepreneurs (5) actively create or disrupt institutions like the rules of 661 662 exchange, shared beliefs and norms (Baker et al., 2019), and market categories (Ozcan & Gurses, 2018).

663 A second extension of marketing studies is to advance away from the single firm-centric notion of shaping markets. Market shaping is now perceived as an inter-stakeholder activity that goes beyond 664 firm-customer engagement (Nenonen et al., 2019). Customers and peripheral actors contribute to 665 preference creation (Slater & Narver, 1998), sometimes even through user innovation (6). In some cases, 666 companies, customers and others engage in collective experimentation and multi-stakeholder co-667 668 creation (7) (Kazadi et al., 2016). This aligns with Lee and colleagues' (2018; 2020) collective perspective of market creation. Such a collective view legitimizes the adoption of a more systemic 669 perspective to markets in marketing studies (Vargo et al., 2017). 670

#### 671 2.3 Sociology of markets

In the sociological literature, markets are defined as "social arenas where firms, suppliers, customers, workers, and government interact" (Fligstein & Dauter, 2007), and in which material and political activities run parallel to discursive processes of creating new frames or consumption categories that have sufficient moral support and cognitive legitimacy from consumers as well as other audiences like regulators. The *material dimension* (3) of markets takes the form of market devices, i.e. new products
(Geiger & Gross, 2018). These new products shape the practices of stakeholders, such as consumers,

and are part of the discursive process.

The discursive dimension emanates from the need for stakeholders to position themselves vis-à-vis 679 680 markets: How do consumers perceive new products and become convinced about the value of products, and how do producers try to act on this (Fligstein & Dauter, 2007)? Consumers form functional, cultural 681 and normative valuations of new products, in which status and familiarity play a key role. Producers 682 reinforce the valuation of new products through "processes of standardization, cognitive anchoring, 683 normative legitimation, and social positioning" (Beckert, 2009). Transcending individual valuation, 684 newly forming markets are associated with new consumption categories that need to find moral support 685 and cognitive legitimacy (8) from consumers as well as other audiences (Aldrich & Fiol, 1994; Navis & 686 687 Glynn, 2010). Entrepreneurs actively engage in these activities by claiming the market as their own, e.g. 688 through identity-based, meaning-making actions (Santos & Eisenhardt, 2009), or by the collective rationalization of symbolic environments in which stakeholders appreciate new meanings and identities 689 (Rao et al., 2003). 690

Market formation from a sociological perspective also involves politics, as actors in markets have certain 691 interests. Incumbent actors strive for stability in established markets, dictating how things are organized. 692 693 This inherently leads to inclusions and exclusions, e.g. consumers whose needs are not met or challenger firms that struggle with existing market regulations (Fligstein, 1996). The degree of inclusiveness and 694 malleability is treated from the perspective of markets as social constructs: spaces with boundaries which 695 696 are continuously reframed and connected to things outside the space, i.e. overflows (Callon, 1998). In 697 some cases, consumers become empowered to articulate their demands (1). Companies also relate to markets strategically (9) by starting to offer products – or terminating such offerings and creating new 698 or destabilizing existing markets in the process. They do this together with other challenger and 699 700 incumbent firms (Ozcan & Santos, 2015), governments and regulators, and societal groups (King & 701 Pearce, 2010). Nascent markets typically feature "undefined or fleeting industry structure [...] and lack of a dominant logic to guide actions" (Santos & Eisenhardt, 2009). Actors need to build new coalitions 702 and structures out of this uncertainty and disorganization (Geiger & Gross, 2018) by establishing 703 704 institutions like property rights, consumer protection and rules of exchange (10).

## 705 **2.4 Transition studies and market formation**

Users, markets and distribution networks are regarded as important in transitions. For example, Kemp 706 707 et al. (1998) wondered why a market for electric vehicles was so difficult to create and sustain, and emphasized the importance of market creation in the context of niches. Creating a market involves 708 establishing rules for safety and quality requirements, property rights, liability, consumption-stimulating 709 subsidies and tax credits for users, and competition (Geels, 2004). In the technological innovation 710 711 system framework, market formation is one of the set of activities ('functions') that contribute to 712 building an innovation system around an emerging technology. Here, market formation concerns mainly 713 two dimensions: articulating who the users and their preferences are, and whether there are institutional 714 barriers that should be overcome for markets to form (Bergek et al., 2008; Hekkert et al., 2007). In 715 reaction to these transition perspectives that more or less start from technological development, Shove and Walker (2007) emphasize consumption activities which recombine technologies to better fit the 716 717 demands of daily life. In doing so, they highlight demand-side actors' logics and practices (11), and 718 their active role in forming use patterns and preferences (1).

Building on this, Dewald and Truffer (2011, 2012) move away from seeing markets as pre-existing and 719 720 waiting to be exploited or covered by firms in an uniform way across geographical contexts. They build on work by, e.g. Möllering (2011), who claims that we should study markets in a systemic and 721 integrative way, not focusing on one element but taking multiple 'devices' into account and how they 722 relate to other parts of the innovation system. Dewald and Truffer (2012) discern three elements that are 723 724 key to market formation. The first is the 'formation of market segments'; this concerns the identification 725 and building of networks of actors and institutions (5; 9) that cover core and complementary aspects of 726 new markets. The second is the 'formation of user profiles'; this relates to the articulation of user 727 preferences (1). These preferences should be regarded in the context of user practices and routines, social responses and status, perceptions and expectations of quality, their willingness to take risks, and 728 729 their flexibility and readiness to adopt a new product and change their practices (Kemp et al., 1998; Truffer, 2003). The third is the 'organization of interactions between producers and users'; how users 730 731 and producers organize the way they interact (10) on the market in a regular way. This requires new 732 rules for commodification, communication and competition to emerge and develop among users and 733 producers (Möllering, 2011).

Recent additions to transition studies advance the active attempts by certain actors to change existing market institutions, as such acting as *institutional entrepreneurs* (5) (Pelzer et al., 2019). In addition to enabling exchange practices and proving the organization of interactions, Ottoson and colleagues (2020) added a cognitive dimension to market shaping by emphasizing the *construction of a narrative* on what a market is about (8). They found that there might be potential tensions between narrative building and envisioned system growth.

So far, we have identified relevant concepts in four bodies of literature. The review shows that many ideas, like demand articulation or dominant and legitimized product categories, return in different literatures, indicating that cross-fertilization has taken place. We numbered the concepts and ideas throughout Section 2 that we use as a basis for the conceptualization of market formation processes in the next section.

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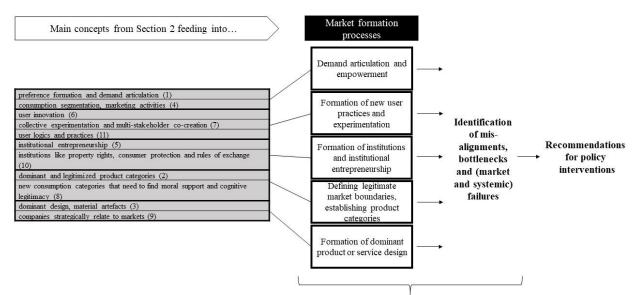
#### 3. Building a framework based on market formation processes

From the literature streams described in the previous section, we construct a conceptual framework with 747 market formation processes, which can be used to capture important dynamics of market formation 748 relevant for transformative innovation policy. As we explained in the introduction, we are inspired by 749 750 the notion of 'functions' as used in the technological innovation system framework. The grey box at the 751 left-hand side of Figure 1 shows how the concepts that we highlighted (and numbered) in Section 2 can 752 be grouped into five specific and distinct processes that capture market formation. We use the key 753 concepts identified in the grey box to define five distinct market formation processes shown in the white 754 boxes of Figure 1 and listed below:

a) Demand articulation and empowerment: This process defines user preferences and links
them to the possibilities created by novel technologies, their applications, and the products or
services they enable, reducing information asymmetries between users and producers in the
process. Producers do this by defining consumption categories and pursuing marketing activities
(Doganova & Karnøe, 2015). Users can also take a proactive role in demand articulation by
lobbying for innovations on their terms and specifying how their needs can be satisfied with
existing technologies (Dewald & Truffer, 2012; Tripsas, 2008).

- b) **Formation of new user practices and experimentation**: This process contributes to learning and feedback when users domesticate an innovation and align it to everyday activities and practices that put constraints on how a new technology or product can be incorporated (Cherunya et al., 2020). Users like consumers and professional buyers engage in experimentation and demonstration to co-create user practices, and might even innovate themselves (von Hippel, 2005).
- c) Formation of institutions and institutional entrepreneurship: This process changes the
  institutions that relate to and support the way in which exchanges in markets are organized, e.g.
  through certification, standardization, rules and regulations (Fligstein & Dauter, 2007). As
  institutional entrepreneurs, stakeholders can take the lead in conceptualizing divergence from
  existing institutions in a way that accommodates the radically new products or services or an
  entirely new way of applying of existing products and services and try to implement these
  changes (Battilana et al., 2009).
- d) Defining legitimate market boundaries and establishing dominant product categories:
  This process frames the boundaries of new markets as part of a socio-cognitive process
  performed by producers, alone or collectively, so that they align with their development and
  diffusion strategies (Ottosson et al., 2020). What names and narratives do they use to explain
  and argue for the existence of the market? This legitimization may consider the efforts of
  individual producers (Santos & Eisenhardt, 2009) as well as anchoring a market as a whole and
  establishing a market category (Navis & Glynn, 2010).
- Formation of dominant product or service design: This process coordinates building dominant designs (Suárez & Utterback, 1995) that form a de facto standard for a product or service and strongly influence how a market is defined. Although dominant designs emerge once markets are maturing, the developments leading up to designs becoming prevalent start earlier, and the establishment of a design co-occurs with developments in the other four processes of market formation.

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Focus of exploration in Section 4

790 **Figure 1:** Steps leading to the conceptualization of market formation processes to improve policy. The numbers

in the grey box at the left-hand side indicate how this framework mobilizes the insights from the literature discussed in Section 2.

The next sections illustrate and further characterize these five processes in more detail, including the way in which they have the potential to identify misalignments, bottlenecks and failures, by exploring three cases of market formation. These cases are used to apply the framework and refine it based on these first lessons.

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#### 798 **4. Exploring market formation processes in three cases**

#### 799 4.1 Methodological approach

We then applied our framework to example cases of technology-based markets in the context of 800 transitions. This approach makes it easier to understand our conceptual arguments and see how they 801 802 could be applied to empirical settings (Siggelkow, 2007). We had two objectives in doing so. First, to 803 illustrate the defined processes and explore their suitability for capturing market formation as 804 technologies emerge. We address the five processes in an open way without a presupposed or implicit order in mind, rather seeing them remaining in a co-evolutionary or iterative relationship. Second, to 805 explore whether they show empirical specificities and how they identify misalignments, bottlenecks and 806 failures in market formation. 807

In line with transition studies, we regard the emergence of technologies as taking place within co-created socio-technical systems, in which regulations, supply networks and infrastructures are co-developed alongside markets and technologies (Geels, 2002). We selected three cases that feature the emergence of (a coherent set of) technologies which are considered by developers, industry experts, users, etc. to contribute to a broader transition. Table 1 shows the cases by emerging technology, the transition to which they contribute, and the key references that explicate why these technologies are expected to lead to transitions.

No	b. Emerg	Emerging technology		Contributing to	o transition		References
1	<u>3D</u>	printing	for	Transition	towards	green	(Despeisse et al., 2017)
	decent	ralized		manufacturing	: change from	n linear	_
	manuf	manufacturing		to circular,	customized	and	
				decentralized	(closer to	home)	
				manufacturing			
2	Direct	-to-consumer		Transition to	wards person	nalized	(Hamburg & Collins, 2010)
	geneti	genetic testing		healthcare: cha	ange from on	e-size-	
				fits-all to tailor	rmade treatm	ents	
3	Digita	l platforms	for	Transition to	owards prev	ventive	(Alonso et al., 2019)
	eHealt	<u>h</u>		healthcare: cl	hange from	cure-	
				centered to	prevention-f	ocused	
				care			

815 Table 1: Overview of the cases.

816

- 817 For each case, we applied a combination of methods including interviews, document analysis, and
- 818 organizing focus groups with key players. We did not, however, follow the same approach in all three
- $cases^1$ . Table 2 presents figures and details on the data collection methods applied in each case.

	3D printing for decentralized manufacturing	Direct-to-consumer genetic testing	Digital platforms for eHealth
Documents analysis	Peer-reviewed literature. Analysis of central market reports (e.g. Wohlers Reports), selected through key informant interviews and confirmed through citation analysis Bibliometric approaches were also applied using the Web of Science, extracting the meta-data, and identifying key articles through citation analysis.	Peer-reviewed literature: key articles (see left). Additionally, we visited key company websites that were mentioned in the articles on which we searched for missions and main technologies.	Key informants from Dutch economic boards and the health ministry provided us access to key policy documents, to lists with eHealth companies (whose websites we searched), and to agendas of innovation acceleration brokers.
Interviews	Semi-structured interviews with 3D printing firms, public research organizations and users of 3D printing equipment. Interviewees were selected based on their centrality in the field (stemming from publication analysis). Participation in central 3D Printing conferences revealed other interesting interview candidates as well as providing additional insights. The number of interviews was determined by how much additional information each interview provided – in this case 20 interviews was sufficient before diminishing knowledge returns was reached.	Semi-structured interviews with medical professionals, reimbursement agencies, regulators that were mainly approached from contacts with the Dutch reimbursement agency which has a central role. Subsequent selection based on stakeholder mapping. 6 interviews in total, lasting on average 60 minutes. Interviews were transcribed.	Semi-structured interviews with eHealth entrepreneurs (3 times over the course of 9 months), care organizations, innovation acceleration brokers, regional innovation agencies. Selection based on actors involved in 3 Dutch regions. 11 cases were each interviewed 2-3 times; interviews lasted on average 20 minutes.
Focus groups	Scenario workshop on the future of 3D printing of biomaterials. This provided insight into the state-of-the-art, needs and	Scenario workshops on the future of genetic testing in which 14 persons participated. Selection of participants based on those	Findings were discussed in a validation workshop in which 7 persons participated who represented public

820 Table 2: Data collection methods used for each case.

<sup>&</sup>lt;sup>1</sup> To ensure the framework is broadly applicable, we did not enforce a particular set of tools or methods to gather data. Instead, we argue that by defining and articulating the dynamics of interest (the five functions) and considering the particular context of the analyzed market formation case, analysts can choose their own methods, as long as they are well reasoned and robust.

	requirements along with expectations of how the field will unfold and challenges and opportunities ahead (as seen from key stakeholders).	expressed interest to join. The workshops aimed at constructing future	investment agencies, the ministry and a few companies.
Others	Participation in standards (Joint ASTM F42 and ISO TC 261) committee meetings, visits to facilities (firms, research centers and Fablabs). Use of a number of databases (SCOPUS for bibliometrics, PatStat for patent analysis and Orbis for analysis of companies and mergers and acquisitions).	N/A	Field visits to meetings of regional innovation agencies on and with eHealth entrepreneurs and care organizations.

821

822 Although the three cases had dissimilar data collection methods, the document analysis (mostly based on key scientific articles and policy documents) as well as information gained during interviews with a 823 824 wide range of different stakeholders, provided a historical perspective and knowledge of the state-ofthe-art. This was laid down in a historical account that was validated in workshops, during which also 825 anticipated future developments, challenges and needs were articulated. Triangulating the outputs of 826 these multiple methods provided a rich and coherent overview of the emergence and potential future 827 evolutions of the three cases. These case overviews were then examined for the market formation 828 829 processes; whether these were present and how they played out. We used the operationalization 830 presented in Table 3 below to help identify the processes.

831 Table 3: Sensitizing concepts for the operationalization of the market formation processes.

Abbreviation	Processes	Sensitizing concepts		
(a) DemandArt	Demand articulation and			
	empowerment	try to explain what they perceive as important		
		preferences and characteristics in relation to an		
		emerging innovation; active lobbying for		
		innovations that align with user preferences		
(b) NewUse	Formation of new user	Define and co-create the everyday context in which		
	practices and	11 / 1		
	experimentation	of an innovation in a real-life context		
(c) InstiTrans	Formation of institutions	0 0 0		
	and institutional	aiming to contribute to transforming existing		
	entrepreneurship	institutions or creating new institutions		
(d) MrktBndry	Defining legitimate	Demarcation process of product categories;		
	market boundaries and	producers aiming for control over product category;		
	establishing dominant	seeking legitimacy with users and governments		
	product categories			
(e) DomDesign	Formation of dominant	Product (or service) development; defining the (core		
	product or service design	and peripheral) characteristics		

Section 4.2 presents the three illustrative cases, identifying the market formation processes as the 833 834 technology emerges. To help the reader, we use the abbreviations shown in Table 3 to indicate where there are details related to a particular market formation process. For example, if the case refers to 835 'Demand articulation and empowerment function', we include the abbreviation [DemandArt]. In 836 837 Section 4.3 we then aim to diagnose the extent to which the identified market formation processes are 838 associated with misalignments, bottlenecks and/or failures. Identification is based on the analysis of 839 documents, interview data and workshops, as recounted in Section 4.2. Especially the workshops were 840 informative, as the main topic of these meetings was to investigate how and under which circumstances 841 future diffusion would take place, starting from bottlenecks in the present.

#### 842 **4.2** Cases

#### 843 *Case 1: 3D printing for decentralized manufacturing*

844 3D printing or additive manufacturing transforms a digital 3D image into a material object through layerby-layer 'printing'. 3D printing can be regarded as the interplay between printing technology, materials 845 to print with, and digital images to create a physical object. At its origin, 3D printing technology 846 847 promised to accelerate product development cycles by making rapid prototypes out of plastic (Bernard 848 & Fischer, 2002; Jacobs, 1992). A rapid prototyping R&D community emerged with its own associations (GARPA – the Global Alliance of Rapid Prototyping Associations<sup>2</sup>) and peer-reviewed 849 journals (e.g. Virtual and Physical Prototyping Journal, and the Rapid Prototyping Journal). The shift in 850 851 the use of 3D printing from rapid prototyping to direct manufacturing was driven by the maturation of key technologies as well as the increasing availability of other materials for 3D printing, such as metals 852 853 and ceramics (Bak, 2003; Frazier, 2014). 3D printing enables circular, customized and decentralized manufacturing and thus has the potential to stimulate green production (Despeisse et al., 2017). 854

Professional users played a major role in co-developing 3D printing technologies for various niche applications. A prominent example of one of the first application areas was the proposition of customized one-off dental prostheses. Tooth prostheses were traditionally standardized, mass-produced whole teeth, tooth-covering and jaw elements. The 'closest fit' was selected from these standardized prostheses and then adapted to the patient's tooth shape and jaw structure by dental surgeons through scraping, shaping, bending etc. Whilst mass-produced prostheses kept the costs of dental surgery relatively low, this also meant that the prostheses were not an optimal fit.

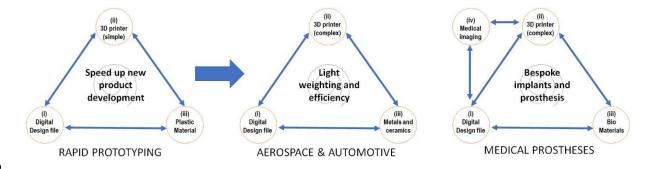
In the late 1990s, dentists saw a potential market for using 3D printing to make patient-specific models 862 and surgical guides to plan and assist procedures (Gibson et al., 2006; Liu et al., 2006; Winder & Bibb, 863 2005). During this period of time, and because of the variety of demonstrations, dentists became 864 increasingly interested in mass customization, and proposed various requirements in terms of consumer 865 needs, technical standards and quality assurance. Custom implant and dental diagnosis was also being 866 867 demonstrated with the use of rapid prototyping for customized dental structures: "A woman had an 868 obvious contour deformity [...] An acrylic stent of the missing tissue was then constructed [using a 3D 869 printer]. With the acrylic stent as guide, the graft from the iliac crest could be precisely shaped and contoured before it was attached to the mandibular angle with titanium screws" (Liu et al.2006, p. 333) 870 [DemandArt]. 871

872 Other dentists then began experimenting with 3D printing (Scherer 2015) to create models of patients' 873 teeth based on medical imaging *[NewUse]*. This evolved into the direct printing of dental prostheses,

requiring feedback loops with 3D printing professionals and new companies entering the dentistry field

<sup>&</sup>lt;sup>2</sup> https://wohlersassociates.com/GARPA.html (accessed 15/12/201)

in order to develop additive manufacturing capabilities. One such companies was Materialise (Belgium), 875 which developed a software system (the Materialise Mimics<sup>TM</sup> software<sup>3</sup>) to translate medical imaging 876 data into a 3D system, thereby enabling the design of dental prosthetics (Liu et al., 2006). Such support 877 systems were essential to enable 3D printing to be effectively used for medical applications. The advent 878 879 of printing with metal rather than plastic, particularly the cobalt-chrome that meets the high-quality standards of dentistry, made direct manufacturing of dental prostheses possible. De facto dominant 880 881 combinations of printers, materials and design software emerged (Robinson et al., 2019) [DomDesign], 882 which were distinct from the combinations that became dominant in other 3D printing markets, like 883 aerospace and automotive industries (Frazier, 2014) (Figure 2). The emerging dominant design broadened the usual practice of dental prostheses design, production and fitting, enabling dentists 884 885 themselves to customize prostheses, like orthodontic models, splints and dentures, and have them available at a much quicker rate [NewUse]. This market was delineated from other 3D printing markets 886 by the development of tailored software for designing implants, and the adaptation of 3D printers to use 887 biocompatible materials, such as cobalt-chrome, by drawing on dentistry standards. Firms such as 888 889 Formlabs (United States) played a major role in this delineation by tailoring the elements of the dominant 890 design of 3D dentistry printing (Figure 2) [MrktBndry]. Key firms like 3D Systems and Materialise straddled multiple markets (for example fashion, aerospace and medical prostheses<sup>4</sup>), advancing 891 technical standards for the printers across markets, while simultaneously tailoring their products and 892 business development accordingly. There was also a cognitive aspect to this delineation of the market, 893 894 as dentists advocated tailormade products as the optimal standard, a move which requires surgeondesigners to be responsible for the creative and skills-based part of the manufacturing process (Dawood 895 et al., 2015)/MrktBndry]. For example, dentists such as Dr. Michael Scherer claimed that "innovation 896 within intraoral optical scanning and 3-D printing should continue to allow clinicians to make complex 897 898 procedures simpler and more efficient" (Scherer 2015, p 8).



899

900 Figure 2: The triad schema of dominant designs for 3D printing in dentistry and for two example markets.

Communities, professional societies and rapid manufacturing industry associations (for example 901 GARPA, see above) emerged along with standardization. As 3D printing evolved and diversified, the 902 production of end-use parts and goods triggered the need for technical interoperability, quality and 903 safety. Direct manufacturing for mass customization required standards to be in place to guarantee that 904 additive process technologies were compatible with existing industrial materials and computer-assisted 905 906 design software. The negotiation of such guarantees started in the late 2000s with national standardization efforts in the United States, France and Germany, and were then applied across all 907 908 existing and emerging 3D printing markets [InstiTrans]. These standardization efforts included the creation in 2009 of the ASTM F42 technical committee on additive manufacturing as a co-production 909

<sup>&</sup>lt;sup>3</sup> <u>https://www.materialise.com/en/medical/mimics-care-suite</u> (accessed 15/12/2021)

<sup>&</sup>lt;sup>4</sup> <u>https://www.materialise.com/en/industries</u> (accessed 15/12/2021)

910 of national standard bodies (i.e. NIST), professional societies (i.e. SME), multinational corporations (i.e.

BMW, Siemens, Stryker & Honeywell), small and medium-sized firms, research universities as well as

federal agencies and research institutes (i.e. NASA, Naval Air Warfare Center, Air Force Research

213 Laboratory). Parallel to the ASTM's efforts, from 2010 onwards, European standardization bodies, such

914 as the French Union de Normalisation de la Mécanique and the German DIN, have also supported the

915 creation of additive manufacturing standards [InstiTrans].

At the same time, niche-specific institutions were introduced. Dental and other medical 3D printing require medically approved materials of a standardized quality and sufficient evidence on safety to support this, so that clinicians and insurance companies can make valid risk assessments. For example, the US Food and Drug Administration<sup>5</sup> started approving the use of digital patient scans in combination with software and a 3D printer in 2013 to produce patient-matched denture teeth by depositing layer upon layer of resin material (Molitch-Hou, 2013) *[InstiTrans]*.

922 <u>Case 2: Direct-to-consumer genetic testing</u>

923 'Genetic testing' is an umbrella term, which covers many types of tests and applications, ranging from 924 newborn screening and carrier testing to pharmacogenetic tests. Genetic testing has seen substantial 925 technological advances over the last 25 years. Since the Human Genome Project finished in 2003, which 926 resulted in the first sequence of a human genome, many generations of genetic test technologies have 927 been introduced. Numerous opinion leaders and firms like Celera Genomics had the ambition to 928 sequence the human genome in a fast, cheap and adequate way, with "the goal of reducing the cost of human genome sequencing to US\$1000" (Heather & Chain, 2016; van Dijk et al., 2014) [DemandArt]. 929 930 Cheaper testing would allow ubiquitous diagnosis and customized treatment. As such, genetic testing 931 forms a pivotal technology in transitioning towards more personalized healthcare (Hamburg & Collins, 932 2010).

Parallel to the technological developments, the applications of genetic tests have changed over the years. In the Netherlands, for example, genetic testing was confined to special clinics that were established as financially separate 'foundations' under the umbrella of university hospitals *[NewUse]* due to the need for control and clinical oversight (Aarden et al., 2010). As a consequence, these clinics became highlyspecialized centers for experimentation and testbeds for new diagnostic technologies (Nelis, 1998) *[NewUse]*.

939 Genetic testing was soon to break out of the clinical context. Cheaper and faster tests sparked the emergence of companies that began to explore the possibilities of offering genetic tests directly to 940 941 consumers, with or without the involvement of medical professionals. Two waves of direct-to-consumer genetic testing companies have since surfaced (Hogarth & Saukko, 2017). The first wave concerned 942 943 firms like Sciona offering dietary recommendations based on a single (or a few) gene mutation(s) 944 associated with nutrient metabolism. Monogenic tests were also part of this wave, like the one offered 945 by Myriad Genetics for breast cancer predisposition genes BRCA1/2. The second wave appeared from 2007 onwards and consisted of companies that began making use of next-generation sequencing 946 technologies, enabling polygenic risk tests for common diseases [DomDesign]. A direct-to-consumer 947 genetic testing sector emerged, which consisted of around 250 firms by 2016 (Phillips, 2016) featuring 948 949 companies like 23andMe as flagships.

The departure from the clinical domain varied by country and for each type of genetic test. Customers had become increasingly "interested in taking control of information and decisions related to their

<sup>&</sup>lt;sup>5</sup> https://www.fda.gov/medical-devices/products-and-medical-procedures/3d-printing-medical-devices

health" (interview result). This empowerment of individuals tied in with using direct-to-consumer 952 953 predisposition tests for common diseases without clinical oversight [DemandArt]. At the same time, our interviews and workshops revealed that clinicians might still be involved considering that the outcomes 954 of genetic tests would lead consumers to general practitioner's offices for explanation, treatment or 955 consolation, increasing the burden on healthcare systems (Boon et al., 2015). A new 'workflow' arose 956 957 in which customers received test kits delivered to their homes, which they should return by mail, after 958 which communication took place mostly online [NewUse]. An online culture of users then emerged, in 959 which the use of the product is shared, e.g. through company-endorsed 'spit parties' on online platforms [NewUse]. Companies like from e.g. Navigenics or 23andMe approached customers, emphasizing the 960 narrative of creating social bonds or exchanging gifts (Harris et al., 2013) [DemandArt]. 961

962 Obviously, these companies and their investors saw the healthcare sector as the main area of application. 963 They focused on carrier testing for monogenic diseases like cystic fibrosis or sickle cell disease, and 964 pharmacogenetic tests that show individual drug metabolism characteristics to guide drug dosage decisions. These tests became standardized [DomDesign], cheap and widespread and, in many 965 countries, sold and used under the guidance of medical specialists or pharmacists. Companies boosted 966 expectations of polygenic risk tests that look for combinations of susceptibility alleles that are associated 967 with a disease and can be used to predict whether an individual will develop it in the future [DemandArt]. 968 The FDA and medical professionals question the predictive accuracy of such tests. They call for 969 "sufficient clinical validity" [DemandArt] and for complementing genetic testing with professional 970 counseling [NewUse]. 971

972 Commercial genetic firms like 23andMe have found it difficult to align their business models with the practices and regulations of the healthcare sector that "is based on hard evidence following from clinical 973 studies". Whether this is due to the 'act first, ask permission later' attitude of start-ups or whether they 974 were simply unfamiliar with the institutional demands in healthcare (Bensinger, 2016), the fact remains 975 976 that such firms came under the regulatory scrutiny of the FDA when entering the market. For example, 977 after its foundation in 2006, 23andMe began offering genetic tests to give health advice. This soon attracted the attention of the FDA, who demanded evidence for the safety and efficacy of such tests. 978 When no such evidence was forthcoming, the FDA ordered the company to stop marketing its product 979 980 in 2013. The company acknowledged that they had failed to comply with regulations, and started investing in evidence gathering and reporting (Hayden, 2017) [InstiTrans]. The story of the struggle of 981 digital-based health companies with regulatory oversight is not limited to 23andMe, but applies to many 982 others as well (Steinberg et al., 2015). 983

984 23andMe and other commercial genetic testing companies survived by diversifying into and creating new (sub-)markets [MrktBndry]. Most closely related to healthcare is the wellness market, in which 985 advice on nutrition and exercise, for example, can be based on genetic traits. Companies such as Helix 986 987 advertised the application of such tests to those particularly interested in a healthy lifestyle and sports, e.g. related to "muscle composition". Another market was formed for people wanting to know more 988 989 about their ancestry, familial proximity, talents and character. Here, companies like Ancestry anticipated consumers' growing interest in identity and race, which has been reinforced through popular culture and 990 991 social media (Marcon et al., 2021) [DemandArt]. By focusing on lifestyle and ancestry, the companies were able to distance themselves from making health claims, which made clinical evidence and 992 993 regulatory licenses less important [MrktBndry].

994 Case 3: Digital platforms for eHealth

995 Digital platforms for telehealth are part of a group of technologies that fall under the term 'eHealth', i.e. 996 IT solutions used in healthcare, which have received commercial attention since the early 2010s (Mihalas et al., 2014). eHealth innovations are associated with the promise of contributing to the 997 998 transition towards preventive healthcare (Alonso et al., 2019). A wide variety of eHealth solutions, like exercise apps for wearables and web portals for remote medical consults have been created and tested 999 1000 across the Netherlands and beyond, indicating that a dominant design has not vet arrived. Some 1001 healthcare experts expect that one or only a few generic healthcare platforms will dominate in the future, 1002 and help to standardize the way eHealth products and services are brought to patients [DomDesign].

1003 At present, small-scale entrepreneurs often start with an idea of how to improve the workflows within healthcare organizations or with patients. They base their idea on their experiences as medical 1004 professionals or as IT specialists seeing business opportunities in healthcare. In the majority of cases, 1005 1006 the idea behind an eHealth innovation concerns tracking health-related indicators and monitoring body functions to prevent diseases developing [DemandArt]. Companies also propose eHealth solutions as a 1007 way to make processes in healthcare organizations or patient-doctor interactions "richer and more 1008 1009 efficient" [DemandArt]. For example, one company delivers digital physiotherapy care to support 1010 patients doing exercises at home, providing information, outcome analysis and video consultation. The 1011 platform helps to fill the gap between when the caregiver sends the patient home and when the patient 1012 returns. The company would like to provide blended care, i.e. a combination of physical and digital 1013 treatments of the patient.

1014 Most eHealth solutions are first tested in small-scale pilots, sometimes even in the form of in-hospital 1015 'field labs'. Scaling up seems to take place slowly or not at all (Greenhalgh et al., 2017), because of a lack of data standardization, interoperability problems, local health insurance regulations, privacy 1016 issues, and evidence of use in real-life contexts, among other reasons (Parente, 2000). As a result, such 1017 1018 pilots often remain local, i.e. inside the hospital, as their results cannot be transferred to other localities 1019 and the eHealth solutions struggle to become sustainable beyond first-mover adopters. The innovation 1020 projects we studied revealed that patients, informal caregivers and medical professionals are not attuned 1021 to and sometimes even "conservative" about using eHealth [NewUse]. Entrepreneurs acknowledge the 1022 importance of involving patients through so-called 'patient journeys', for example, although only during 1023 late-stage prototyping [DemandArt].

According to our respondents, the most prominent barrier to scale is that the regulations for reimbursement must be organized differently to enable not only supplementary but also substitution of physical therapy with the digital platform *[InstiTrans]*. Health insurers do not yet reimburse this, which is partly due to the conditions set by the government as well as the way in which the professional association defines good clinical practice *[NewUse]*.

1029 Despite difficulties in scaling, there seem to be three established 'exit routes' that we distinguished in the innovation projects we studied: direct-to-consumer (e.g. measuring personal health through simple 1030 1031 indicators on a mobile phone app), one mediated and sanctioned by medical professionals (e.g. the 1032 physiotherapy platform), and platforms at the level of healthcare organizations (e.g. taking the form of 1033 patient information systems). These routes seem to indicate three separate (sub-)markets, each with their own rationale: direct-to-consumer focuses on health-conscious consumers, whereas doctor-mediated 1034 and platform-based eHealth products are often part of established diagnostic and therapeutic workflows 1035 1036 [MrktBndry]. The routes also reflect the respective regulations and norms: direct-to-consumer products 1037 are paid for by consumers, e.g. through app stores. The doctor-mediated eHealth products must be integrated into the standard care and guidelines of medical professional associations to become eligible 1038 1039 for health insurance reimbursement. Inclusion in such guidelines requires gathering data on efficacy and safety [InstiTrans]. Companies struggling with legislation and regulations sometimes try to change these
rules and norms, especially when medical professional associations have vested interests in not
including eHealth products in their guidelines and may have an "inhibitory effect" [InstiTrans].

#### 1043 **4.3** Market formation functions as a diagnostic tool

We are interested in diagnosing misalignments, bottlenecks and failures when technology-based markets emerge in the context of transitions. Based on the three described cases (see Appendix A, Table A.1 for a comparison of cases with the market formation functions), we answer three questions to explore to what extent our framework is able to come to such diagnosis.

1048 First, are the market formation processes distinct and comprehensive enough? The processes point to distinct issues about emerging markets. The 'Demand articulation and empowerment' process shows 1049 1050 how various actors, especially companies, consumers, and industry experts, advance ideas and 1051 preferences about products/services. Often, these ideas take the form of shared broad expectations. In 1052 some cases, these demands are contested (genetic testing). 'Formation of new user practices and 1053 experimentation' organizes how products/services are embedded in everyday life or professional 1054 workflows. Users often interact with suppliers (3D printing in dentistry; eHealth) or companies predefine how workflows should be organized (genetic testing). In the context of 'Formation of 1055 institutions and institutional entrepreneurship', all three cases show companies fighting the vested 1056 1057 interests of incumbent companies or professions. Companies are mostly involved in pro-actively 'Defining legitimate market boundaries and establishing dominant product categories' as a way to create 1058 moral support and legitimacy. The three cases show the definition of new 'exit routes' (eHealth) or 1059 1060 diversification into, and creation of narratives about various possible markets (3D printing; genetic 1061 testing). The 'development of dominant designs' process focuses on the development of a de facto 1062 standard for an innovation. The cases show that this concerns technologies as well as ancillaries, service 1063 provision channels, workflows, etc. One could view this as an architecture, platform or configuration 1064 that develops around the technology and consists of modules open to further development and variation, 1065 as was the case with the printer-materials-software model in 3D printing.

Whether the set of five processes is comprehensive enough is difficult to tell, because there might be 'unknown unknowns'. However, although the methodological approach always included open questions that could have gone beyond the five processes, in no case did we find aspects of market formation that were not covered by the five processes. At the very least, we can say that the processes in combination cover all the relevant aspects identified in the data.

1071 Second, to what extent do the functions resonate and/or interact with each other? The cases showed 1072 a number of interactions between processes. To give some examples, vested institutions in existing 1073 markets lead companies to redefine the markets they want to address and create new markets. For 1074 instance, commercial genetic testing did not gain a foothold in healthcare markets and needed to diverge 1075 into lifestyle platforms and ancestry testing. The boundaries were defined subsequently with the help of 1076 the demands that had been articulated. The 3D printing case showed that the emergence of a dominant 1077 design simplified the use of and experimentation with 3D printing, which led dentists to co-create new 1078 solutions and practices.

To go one step further, not only do the activities related to the processes interact, they seem to do so in a certain order, underlining the dynamic character of emerging markets. For example, all three cases had to deal with strict regulations and norms invested in by incumbent companies and professions. Rearticulating preferences and expectations, experimenting and developing workflows and practices, and diverging and (re)defining markets led to either incorporation or circumventing existing institutions.
 However, it is not possible to infer any dominant logic of function interaction from these three cases.

1085 Third, does the framework of market formation functions indicate particular misalignments, 1086 bottlenecks and failures? The cases demonstrate how the framework can identify and differentiate 1087 misalignments, bottlenecks and failures in the market formation process. We presented the (potential) 1088 failures and policy interventions in Appendix A, Table A.1. In general, they include non-diffusion of practice beyond certain pilots (eHealth), difficulty in re-orientation of the profession (3D printing; 1089 1090 genetic testing; eHealth), misalignment between expected vs. offered quality standards (genetic testing; 1091 eHealth), using legitimization efforts and market boundaries to push for solutions that are ill-aligned 1092 with societal interests (genetic testing), and questions about who should reimburse the product (eHealth). 1093 Although in the Appendix we indicated the potential failures per market formation process, it is clear 1094 that failures may result not from one distinct process, but - as indicated in the previous paragraph - from 1095 an interplay between those processes. For example, dealing with strict regulations and subsequent 1096 (re)creation of market boundaries, practices, etc. indicates a misalignment.

Based on the explorative comparison, we close by discussing the market formation functions and their
use in a functional framework for characterizing and analyzing different processes of new market
formation in the context of transitions.

1100

#### 1101 **5. Discussion**

1102 The purpose of this paper was to develop a framework for characterizing and analyzing processes of 1103 new market formation in the context of transitions. We use the three questions posed in the previous 1104 section to discuss the proposed framework.

1105 First, based on the explorative and illustrative cases in the previous section, we showed that the *five* 1106 market formation processes are distinct to a certain extent. Of course, some events are difficult to 1107 attribute as they might cover more than one process. Still, the processes allow for tracking market 1108 emergence in a more detailed way and analyze emergence with distinct and differentiated, yet intertwined questions. Questions for further research would be whether the list of market formation 1109 1110 processes is complete, or requires further elaboration. For example, one could make a case for a stronger 1111 link between 'defining legitimate market boundaries and establishing dominant product categories' and 1112 the construction of visions and missions in the context of the transitions that these markets are part of 1113 (Hekkert et al., 2020; Markard et al., 2016).

Second, the cases indicate patterns of events underlying the market formation processes in emerging 1114 1115 markets. In general, we might be able to plot the occurrence of activities representing the five processes 1116 over time, accounting for and emphasizing the dynamic side of market formation. This would also open up work on the timing of policy interventions for market formation. Importantly, there is no natural 1117 order or linear stage model implied by the five processes, neither is there a dominant process that serves 1118 1119 as an obligatory passage point. However, the cases do show how the manifestation of certain processes 1120 subsequently influences the form and dynamics of further processes. For example, we have seen that demand-side institutions like professionals, norms and reimbursement criteria are hindering the 1121 1122 formation of new markets, which requires increased efforts of demand articulation and the re-orientation of market boundaries. Such patterns seem to point to chains of events, reflected in the market formation 1123 1124 processes, which reinforce themselves and lead to positive or negative outcomes. These functions interact and may form virtuous or vicious cycles and even 'waiting games' or Catch 22 situations 1125

- 1126 (Robinson et al., 2012). It will be useful to study successful and unsuccessful market formation with the
- five processes framework in order to identify these emerging patterns (Hyysalo et al., 2018; Ottosson et
- 1128 al., 2020).

1129 Besides the patterns, in all three cases, we saw that markets are not formed in isolation. Actors might 1130 strategically move to adjacent markets or are influenced by developments (e.g. emerging dominant 1131 designs) in neighboring markets. Markets are inter-linked in wider 'ecologies of markets' and acknowledging this has broader repercussions for transition studies, as transitions are an interplay of 1132 multiple, intertwined market formations, as in the case of the circular economy. The important lesson 1133 here is that markets are not isolated, institutional arrangements, but emerge in a context of rival or 1134 complementary production and use contexts (Schanz et al., 2019). Furthermore, the notion of markets 1135 1136 could be broadened to include other ways of exchange that are based on public or non-monetized 1137 transactions (Nelson & Winter, 1977) and include alternative, informal, community-based environments 1138 (Feige, 1990; von Hippel, 2005).

1139 Our cases already show how the five processes framework allows a much more differentiated 1140 understanding of how emerging markets interact with other markets. For example, demand articulation 1141 in commercial genetic testing for healthcare purposes resonated with demand articulation in the lifestyle and ancestry markets, and, as we have seen above, institutional pressures led companies to sidestep into 1142 1143 these lifestyle and ancestry markets. Applying our framework will enable us to delve more deeply into 1144 these patterns of market formation and interaction with other markets in the future. Since we only applied the processes to three cases, the next step should be a more widespread application of the 1145 1146 framework to a larger number of case studies, both emerging and retrospective ones, and the aggregation 1147 of the findings.

1148 As we have mentioned in the introduction, in this contribution we have restricted ourselves to a 1149 technology-based market formation. Of course, non-technology-based market formation may also play a key role in transformative change. To elaborate on this point, one could explore how the non-technical 1150 sources of innovation, such as social innovation and organizational innovation, may lead to new market 1151 1152 formation, for example in relatively new markets such as the sharing economy, certified organic food markets and emissions trading. We suggest that the market formation processes developed and 1153 demonstrated in this paper will be useful for analyzing non-technology-based markets, however, we also 1154 1155 agree that further work is needed to explore whether further processes, not visible in technology-based 1156 market formation, are at play and will have to be conceptualized. This is a line of enquiry, which we 1157 will pursue.

1158 Third, as we have argued, market formation processes can reveal constellations and circumstances that are detrimental to the emergence of markets in transitions. Being able to pinpoint *misalignments*, 1159 1160 bottlenecks and failures opens up opportunities for dedicated transformative policy to overcome them. 1161 We located our article in the broader discourse of transformative and systemic change and the role of 1162 policy (Schot & Steinmueller, 2018). We started from the perspective that the grand societal challenges 1163 require transformative changes that cannot take place without the formation of new markets. It is the 1164 increasing policy emphasis on market shaping and creating, as opposed to market fixing (Robinson & Mazzucato, 2019) that necessitates a deeper understanding of market formation processes, and possible 1165 policy interventions. Even where markets seemed to emerge without any deliberate public policy 1166 1167 intervention, as was the case in many digital transformation innovations such as ridesharing and home-1168 sharing, governments were still forced to intervene later on (Frenken & Schor, 2017). Therefore, it seems 1169 highly plausible that public policy must deal with market formation sooner rather than later, either to push a societally desirable technology or to steer the market more generally in a socially desirable 1170

direction. This resonates with the calls to work on "anticipating and learning about user needs", which Weber and Rohracher (2012) marked as 'demand articulation failure' in the context of tackling grand societal challenges, and on promoting demand-side innovation policy measures (Boon & Edler, 2018; Edler & Georghiou, 2007). In consequence, there is a need for a framework to trace market formation from early stages of technology emergence onwards and in real-time, to preconceive what these technologies mean for niche but also future mass markets.

We can now turn to what our concept means for policy. A major role for transformative policy is to help 1177 reduce uncertainty for all market actors across all five functions, to create transparency, to support 1178 directionality, discourse and interaction, and to provide regulatory frameworks that are flexible enough 1179 to allow further adjustments in the formation process, but provide sufficient stability for potential 1180 1181 producers and users. We propose that based on our market formation concept, one can underpin 1182 transformation oriented innovation policy with a more systemic understanding of market formation 1183 processes and a thorough diagnosis of potential misalignments, bottlenecks and failures. Those dysfunctionalities of the market formation processes then present entry points for policy intervention. 1184

1185 The more public policy seeks to steer innovation and market formation in a specific direction, the more important it is to understand the subtleties of market formation across the five functions in order to tailor 1186 intervention accordingly. So far, the market and innovation uptake diagnosis is often poor and the focus 1187 1188 is mainly on lowering the price for innovative technologies through subsidies and tax reductions (Edler, 1189 2016). However, as we have shown in this article, the market formation process and associated misalignments, bottlenecks and failures are much more complex and differentiated than too high costs 1190 1191 for an innovation. As for policy intervention measures, we present some examples in Appendix A, although they are not based on rather than inspired by our cases. These examples demonstrate that the 1192 toolbox of demand-side innovation policy (Creutzig et al., 2018; Edler & Georghiou, 2007; Edquist & 1193 1194 Hommen, 1999) and related policy instruments could thus be further developed and tailored more 1195 effectively to specific market formation circumstances.

Potential directions for policy intervention to be developed follow from the five market formation 1196 1197 processes. A slow innovation uptake can, for example, be caused by a poor articulation of demand in early stages, thus hampering the design of technological solutions that are much more in line with market 1198 1199 expectations. Anticipating future demand and supporting its articulation may thus be the most 1200 appropriate policy intervention. One can imagine process-informed foresight to help anticipate the future 1201 market challenges around competing and potentially disruptive technologies. Equally, slow market 1202 formation can have its roots in the *poor adaptation of user practices* caused by deeply embedded 1203 practices and lack of awareness of the positive benefits of a new technology. Here, in addition to 1204 awareness raising and training measures, experimentation moderated and supported by the state would be required to challenge users and enable them to learn. Further, new regulations may be needed to 1205 1206 establish novel workflows. In this context, new technologies often raise concerns about what constitutes this new market, what the normative standards and the *legitimacy of market boundaries* are. Policy 1207 1208 interventions here would have to focus on an open and transparent discourse about the concerns and hopes associated with technological innovations and the transition they support, leading to a higher level 1209 1210 of acceptance or further modifications in order to increase their legitimacy. Often, the demarcation of 1211 legitimate market boundaries resonates with *institutional configurations in existing markets* that may 1212 hamper the coming together of new demand and new supply. This may be especially the case if 1213 technologies are characterized by a high level of complexity and thus a high level of uncertainty in terms of which actors are entitled to which parts of the market. This necessitates regulatory clarifications on 1214 1215 property rights and the rules of exchange, potentially accompanied by regulatory sandboxes to allow for the development of appropriate regulation. This is strongly related to the establishment of dominant 1216

- *designs* that will shape the final market. Often, this happens through market forces alone in forming de facto standards. However, the state may intervene in order to speed up this process, influence the direction of standardization and ensure de facto standards are in line with the regulations that shape market formation as a result of the market formation discourse. The development and deployment of dominant designs can be pushed through public procurement. In the appendix, we illustrate the demandside bottlenecks and possible policy interventions along our three cases. These illustrations show how the five functions can be used separately or in combination to guide policy intervention that supports
- 1224 the entire market formation process.

#### 1225 **6.** Conclusions

Our approach to market formation is informed by complementary theoretical perspectives. By 1226 combining these perspectives in a functional framework covering five market formation processes, we 1227 are able to advance the study of market formation in the context of transformative policy. The 1228 advancements are in line with calls for taking a process perspective (Dewald and Truffer, 2012), for 1229 1230 opening the black box of forming markets (Bergek et al., 2015) and especially elaborating on the demand-side of markets which is currently under-addressed in transformative innovation policy (Weber 1231 1232 and Rohracher, 2012). This enables us to capture the systemic, contextualized nature of the market 1233 formation process from early phases of technology emergence onwards, and can use this to study and 1234 design market-shaping policies that contribute to desired transitions. This, then, could become an 1235 essential element to meet the "operational intelligence requirements" which have been diagnosed as major prerequisites for appropriate and legitimate polices to support demand and market formation. 1236 1237 (Boon and Edler 2018, p. 439).

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# 1560 Appendix A

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1562 Table A.1: Comparison of cases with the market formation functions.

<b></b>			
	1. 3D printing for decentralized	2. Direct-to-consumer genetic testing	3. Digital platforms for eHealth
	manufacturing		
Demand	Improvements in speed, accuracy and cost	Producers strove for fast and cheap tests and	Entrepreneurs often have their own ideas,
articulation and	in 3D printing for rapid prototyping	branded their products as making healthcare	which in some cases originate in their own
empowerment	generated interest among professional users	more personalized and empowering	experiences as medical professionals. They
	in various sectors, e.g. dentistry. They are	individuals to take control of their lives in	acknowledge the importance of involving
	interested in mass customization, based on	terms of disease susceptibility and	patients, but organize e.g. so-called 'patient
	different requirements in terms of consumer	prevention. Clinicians asked for clinical	journeys'. The articulated benefits include
	needs, technical standards and quality	validation.	disease prevention (for consumers) and
	assurance.	(Potential) failure: technology providers	making patient-doctor interactions more
	(Potential) failure: development of	fail to understand the performance	efficient (for healthcare professionals).
	technologies following demands of (too)	expectations of users, in particular	(Potential) failure: co-generation of
	select group of active surgeon-designers.	because users (consumers, healthcare	expectations between diverse groups of
	Some preferences might become	professionals) have different preferences.	users and suppliers of new technologies
	overlooked, e.g. in relation to green	Policy: early, interactive development of	not taking place. Especially not on the
	manufacturing.	performance standards that meet	level of understanding of underlying
	Policy: reduction of information	medical (evidentiary) standards.	values and norms.
	asymmetries through awareness	incurcui (criticiul y) stantui ust	Policy: organizing processes of mutual
	campaigns and process-informed		expectation management.
	foresight.		expectation management.
Formation of new	Dentists began experimenting with rapid	Genetic tests were offered directly to	Pilots play a major role but often remain
user practices and	prototyping with specialized materials for	consumers without involving clinics. This	local; pilot results are not transferred to
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experimentation	teeth (metals and ceramics) for customized	triggered new forms of interactions between	other localities and pilots struggle to
	prostheses. This required feedback loops	test providers and users without the	become sustainable after first-mover
	with 3D printing professionals in order to	involvement of the medical profession. An	adopters; practices of patients, informal
	develop the required additive	online culture of product users has emerged.	caregivers and medical professionals are not
	manufacturing capability. 3D printing	Clinicians find it important to complement	attuned to and sometimes even conservative
	enabled dentists to customize prostheses	testing with professional counseling.	about using eHealth; training is needed and
	themselves.	(Potential) failure: as on the left, plus:	they need to redefine what 'good care' is.
	(Potential) failure: joint user-supplier	quality control in area of sensitive	(Potential) failure: lack of scaling up and
	experimentation in a late stage of the	technologies (health and safety, ethical	diffusion of innovative solution. Poor
	technology development to define the	considerations).	competencies on the user side and
	optimal functions of the innovation in	Policy: as left, plus regulatory bodies and professional bodies must be mobilized to	cultural and practice 'lock-in'.

Formation of institutions and institutional entrepreneurship	different user contexts, in protected spaces if needed. Policy: regulatory sandboxes and public demonstrators. Communities, professional societies and rapid manufacturing industry associations emerged along with standardization. Regulation discussions on manufacturing end products, e.g. regulatory approval, IP- issues related to the design files. 3D printing standardization is occurring above and across the individual, product-focused markets. (Potential) failure: techno-centric standardization processes may favor certain preferences or design criteria. This may lead to creation of markets that do not align well with societal goals like sustainability. Policy: state support of standardization activities, early involvement of state	identify any regulatory issues early on to prevent misaligned technology been rolled out with negative market creation effects. Companies struggle with regulatory authorities as they see genetic testing as a new market space that should not be governed by healthcare-related regulations. Regulatory agencies and clinicians uphold strict regulations and norms. Companies more or less comply with norms. (Potential) failure: existing regulatory framework and regulatory practices hinder new practices and adoption of personalized medicine. Path dependencies deter innovative adopters. Policy: awareness within regulatory bodies concerning their responsibilities for adjusting regulation and engaging with emerging market actors.	Policy: awareness raising initiatives, user training, demand subsidies to cover learning costs with users. Companies struggle with legislation and regulations, especially with arranging reimbursement for eHealth innovations, flaws in the real or perceived rules, and becoming part of the guidelines of medical professional associations. Many entrepreneurs are trying to convince institutions to change; only some are successful. (Potential) failure: existing regulatory framework is not able to accommodate preventive medicine innovations. Policy: create regulatory sandboxes and/or alternative reimbursement schemes for preventive measures.
Defining legitimate market boundaries and establishing dominant product categories	regulatory bodies. 3D printing has matured into a number of sub-sectors: dentistry and prosthetics, unique 3D shapes in the automotive and aerospace industry, etc. The customized approach allows dentists to display their creativity and craftsmanship. (Potential) failure: the division of responsibilities becomes vague: what is the remit of 3D printing companies and of dentists? And does this lead to the erosion of the dentistry profession? Policy: through healthcare quality inspectorates division of tasks can be guaranteed.	Companies are striving to create a new market for genetic consumer tests that cover multiple, related services, ranging from disease propensity to ancestry information. They actively differentiate these from healthcare. (Potential) failure: innovation solutions are trapped in their original niches, lack of spread of user value across different potential areas and sectors. Policy: together with producers and users co-create a narrative around personalization.	There are three major strategic market 'exit routes': direct-to-consumer, mediated and sanctioned by medical professionals, and arranged at the level of healthcare organizations. The choice of route dictates to a large extent how other market formation functions play out, e.g. what regulations are applicable. (Potential) failure: each type of market pathway has downsides regarding upscaling potential and/or expected revenues. Policy: a tailored preventive healthcare pathway should be established and legitimized, e.g. requiring new regulations.

<i>Formation of</i> The dominant design is the triad interplay of	Next-generation sequencing technologies	There are many eHealth solutions that have
dominant product printing technology, materials and digital	now enable polygenic risk tests for common	been created and tested across the
or service design design with specific requirements based on	diseases. The testing service has emerged	Netherlands and beyond, indicating that a
the respective subsectors (dentistry,	with a clear digital component:	dominant design has not yet arrived; some
automotive etc.).	communication with customers is done via	expect a more encompassing and generic
(Potential) failure: there is no dominant	websites, information is conveyed through	healthcare platform to arrive in future.
product or service emerging, the lack of	online tutorials, and test kits are home	(Potential) failure: who is leading (and
which opens up questions on how policy		benefiting from) standardization?
could intervene in 3D printing. The	of activities between company and	Public, private and professional lead-outs
analysis suggests that perhaps a focus on	customer have become standardized across	all have their downsides, e.g. in terms of
application-centric 3D printing is more	the industry.	accessibility for new players.
appropriate than techno-centric 3D-	(Potential) failure: a few of the manifold	Policy: attempt to create an open-access
printing (focusing on the printers).	processes, competencies and	platform that ensures a level-playing
Policy: state regulation and procurement	infrastructure items to be in place for a	field.
can push for dominant designs, but with	solution become a dominant design that	
caution and right timing, not closing	works in the market place.	
down variety.	Policy: state to analyze the needs for the	
	development into dominant design roll	
	out and tackle deficiencies.	