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508 **Conceptualizing market formation for transformative**
509 **policy**

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518

519

520 **Abstract**

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

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

530

531 **1. Introduction**

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

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

545 However, how markets are formed in transitions have for long been subjected to rather cursory
546 treatment. First, market formation is often studied in terms of which user groups to target and how to
547 improve innovation adoption, in essence taking a diffusion perspective (Boon et al., 2020; Loorbach et
548 al., 2020; Rogers, 2003). Such a diffusion perspective treats upscaling as an inevitable, linear process.
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
554 understood in the context of the underlying structures and processes of legitimization with which the
555 policy interferes. While highly insightful and important, such case studies, however, do show that there
556 is the need to a more systematic and differentiated conceptualization of the market formation phase.

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

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

574 For transformative policy, while there are a wide variety of innovation types and sources that may
575 contribute to solving grand societal challenges, new technological innovations hold great promise to
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
579 (applications of) technologies despite being aware of the relevant nuances related to venturing into new
580 sectoral, demographical or geographical contexts. We did so because technological solutions often
581 promise to shape and drive future transitions, as they have in the past (Geels, 2002). Further, we see this
582 focus on technological innovations as a first step towards a broader understanding of market formation
583 which would have to include new business models and social innovations that support transformations
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

590 the emergence of markets inevitably must be a concern for governments as they are interested in solving
591 societal problems and are able to regulate or push market creating processes that the interplay of private
592 actors alone cannot advance. So, we want to advance thinking about markets and already start
593 considering markets in the emergence phase of technologies. We also complement and contribute to the
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
598 addressed the role of so-called ‘moral markets’ in dealing with societal challenges and wicked problems
599 (Georgallis & Lee, 2020; Nenonen et al., 2021) and the understudied role of technology as a basis for
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
604 processes and describe its stepwise development. We then demonstrate how the framework can act as
605 an advanced diagnostic tool that provides useful insights into market formation processes using three
606 illustrative cases (Section 4). We close the paper by, first, reflecting on the ramifications of our findings
607 for transformative innovation policy that seeks to support market formation in the context of politically
608 and societally desired transformations, and, second, outlining next steps to test and further develop our
609 framework for analyzing new market formation processes (Section 5).

610

611 **2. Existing perspectives of market formation**

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

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

626 To explain how innovations come about, evolutionary economics has gone beyond perceiving markets
627 as trade arenas in which buyers and sellers with rational preferences and full information maximize
628 utility and profits. Product innovation is regarded as the result of interactive learning between users and
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
631 innovations is created, adopted and retained, and therefore as selection environments for innovations
632 (Bleda & Del Río, 2013; Nelson & Winter, 1977).

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

640 Evolutionary economics then evolved and increasingly considered the demand side and interactions with
641 users. A critical level of consensus is required about how the product should be used and which
642 preferences are met (Benner & Tripsas, 2012). Tripsas (2008) underlines consumers’ uncertain and
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
646 emergence of a *dominant design* (3). Such dominant product categories include “the attributes, benefits,
647 and usage conditions with which products must comply to be considered members in good standing”
648 (Rosa et al., 1999) and draw cognitive boundaries around product markets.

649 **2.2 Marketing studies**

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

654 Recent marketing studies have explicitly moved away from the notion of markets as pre-existing
655 exchange modes or customer segments with fixed preferences (Kindström et al., 2018). They emphasize
656 the endogenous and open-ended nature of markets (Kjellberg et al., 2015) and view market creation as
657 ongoing processes that actors can influence (Nenonen et al., 2019). Preferences are not static and are
658 formed by *demand articulation* (1). Demand uncertainty decreases as product categories become
659 coherent and legitimate and companies or governments can educate consumers about a product’s
660 meaning and use (Doganova & Karnøe, 2015). Moreover, markets are regarded as co-evolving with
661 institutions: *institutional entrepreneurs* (5) actively create or disrupt institutions like the rules of
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
664 shaping markets. Market shaping is now perceived as an inter-stakeholder activity that goes beyond
665 firm-customer engagement (Nenonen et al., 2019). Customers and peripheral actors contribute to
666 preference creation (Slater & Narver, 1998), sometimes even through *user innovation* (6). In some cases,
667 companies, customers and others engage in *collective experimentation and multi-stakeholder co-*
668 *creation* (7) (Kazadi et al., 2016). This aligns with Lee and colleagues’ (2018; 2020) collective
669 perspective of market creation. Such a collective view legitimizes the adoption of a more systemic
670 perspective to markets in marketing studies (Vargo et al., 2017).

671 **2.3 Sociology of markets**

672 In the sociological literature, markets are defined as “social arenas where firms, suppliers, customers,
673 workers, and government interact” (Fligstein & Dauter, 2007), and in which material and political
674 activities run parallel to discursive processes of creating new frames or consumption categories that
675 have sufficient moral support and cognitive legitimacy from consumers as well as other audiences like

676 regulators. The *material dimension* (3) of markets takes the form of market devices, i.e. new products
677 (Geiger & Gross, 2018). These new products shape the practices of stakeholders, such as consumers,
678 and are part of the discursive process.

679 The discursive dimension emanates from the need for stakeholders to position themselves vis-à-vis
680 markets: How do consumers perceive new products and become convinced about the value of products,
681 and how do producers try to act on this (Fligstein & Dauter, 2007)? Consumers form functional, cultural
682 and normative valuations of new products, in which status and familiarity play a key role. Producers
683 reinforce the valuation of new products through “processes of standardization, cognitive anchoring,
684 normative legitimation, and social positioning” (Beckert, 2009). Transcending individual valuation,
685 newly forming markets are associated with *new consumption categories that need to find moral support*
686 *and cognitive legitimacy* (8) from consumers as well as other audiences (Aldrich & Fiol, 1994; Navis &
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
689 rationalization of symbolic environments in which stakeholders appreciate new meanings and identities
690 (Rao et al., 2003).

691 Market formation from a sociological perspective also involves politics, as actors in markets have certain
692 interests. Incumbent actors strive for stability in established markets, dictating how things are organized.
693 This inherently leads to inclusions and exclusions, e.g. consumers whose needs are not met or challenger
694 firms that struggle with existing market regulations (Fligstein, 1996). The degree of inclusiveness and
695 malleability is treated from the perspective of markets as social constructs: spaces with boundaries which
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*
698 *markets strategically* (9) by starting to offer products – or terminating such offerings and creating new
699 or destabilizing existing markets in the process. They do this together with other challenger and
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
702 of a dominant logic to guide actions” (Santos & Eisenhardt, 2009). Actors need to build new coalitions
703 and structures out of this uncertainty and disorganization (Geiger & Gross, 2018) by establishing
704 *institutions like property rights, consumer protection and rules of exchange* (10).

705 **2.4 Transition studies and market formation**

706 Users, markets and distribution networks are regarded as important in transitions. For example, Kemp
707 et al. (1998) wondered why a market for electric vehicles was so difficult to create and sustain, and
708 emphasized the importance of market creation in the context of niches. Creating a market involves
709 establishing rules for safety and quality requirements, property rights, liability, consumption-stimulating
710 subsidies and tax credits for users, and competition (Geels, 2004). In the technological innovation
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
716 and Walker (2007) emphasize consumption activities which recombine technologies to better fit the
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).

719 Building on this, Dewald and Truffer (2011, 2012) move away from seeing markets as pre-existing and
720 waiting to be exploited or covered by firms in an uniform way across geographical contexts. They build
721 on work by, e.g. Möllering (2011), who claims that we should study markets in a systemic and
722 integrative way, not focusing on one element but taking multiple ‘devices’ into account and how they
723 relate to other parts of the innovation system. Dewald and Truffer (2012) discern three elements that are
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,
728 social responses and status, perceptions and expectations of quality, their willingness to take risks, and
729 their flexibility and readiness to adopt a new product and change their practices (Kemp et al., 1998;
730 Truffer, 2003). The third is the ‘organization of interactions between producers and users’; how users
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).

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

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

745

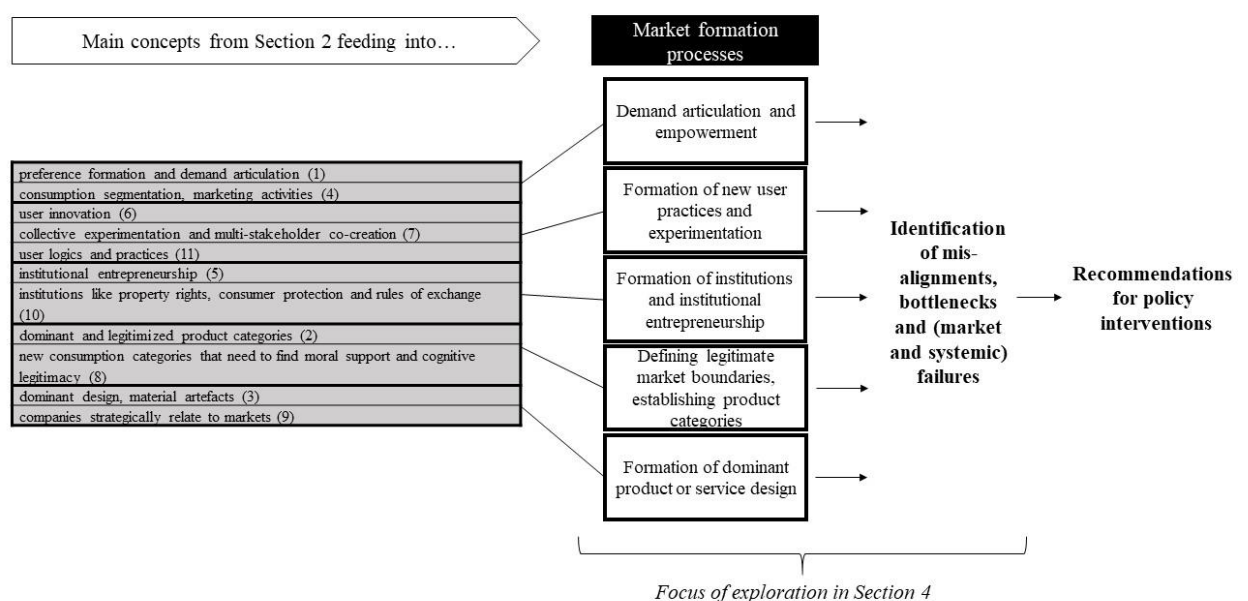
746 3. Building a framework based on market formation processes

747 From the literature streams described in the previous section, we construct a conceptual framework with
748 market formation processes, which can be used to capture important dynamics of market formation
749 relevant for transformative innovation policy. As we explained in the introduction, we are inspired by
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:

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

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

788



789

790 **Figure 1:** Steps leading to the conceptualization of market formation processes to improve policy. The numbers
 791 in the grey box at the left-hand side indicate how this framework mobilizes the insights from the literature
 792 discussed in Section 2.

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

797

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

799 ***4.1 Methodological approach***

800 We then applied our framework to example cases of technology-based markets in the context of
 801 transitions. This approach makes it easier to understand our conceptual arguments and see how they
 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
 805 order in mind, rather seeing them remaining in a co-evolutionary or iterative relationship. Second, to
 806 explore whether they show empirical specificities and how they identify misalignments, bottlenecks and
 807 failures in market formation.

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

815 Table 1: Overview of the cases.

No.	Emerging technology	Contributing to transition	References
1	<u>3D printing for decentralized manufacturing</u>	Transition towards green manufacturing: change from linear to circular, customized and decentralized (closer to home) manufacturing	(Despeisse et al., 2017)
2	<u>Direct-to-consumer genetic testing</u>	Transition towards personalized healthcare: change from one-size-fits-all to tailormade treatments	(Hamburg & Collins, 2010)
3	<u>Digital platforms for eHealth</u>	Transition towards preventive healthcare: change from cure-centered to prevention-focused care	(Alonso et al., 2019)

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
 819 cases¹. Table 2 presents figures and details on the data collection methods applied in each case.

820 Table 2: Data collection methods used for 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

¹ 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).	interview respondents who expressed interest to join. The workshops aimed at constructing future innovation pathways.	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
823 on key scientific articles and policy documents) as well as information gained during interviews with a
824 wide range of different stakeholders, provided a historical perspective and knowledge of the state-of-
825 the-art. This was laid down in a historical account that was validated in workshops, during which also
826 anticipated future developments, challenges and needs were articulated. Triangulating the outputs of
827 these multiple methods provided a rich and coherent overview of the emergence and potential future
828 evolutions of the three cases. These case overviews were then examined for the market formation
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	Iterative, inherently creative process in which users 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 practices and experimentation	Define and co-create the everyday context in which the innovation is supposed to be used; pilot the use of an innovation in a real-life context
(c) InstiTrans	Formation of institutions and institutional entrepreneurship	Initiate divergent changes in a field of activity, aiming to contribute to transforming existing institutions or creating new institutions
(d) MrktBndry	Defining legitimate market boundaries and establishing dominant product categories	Demarcation process of product categories; producers aiming for control over product category; seeking legitimacy with users and governments
(e) DomDesign	Formation of dominant product or service design	Product (or service) development; defining the (core and peripheral) characteristics

832

833 Section 4.2 presents the three illustrative cases, identifying the market formation processes as the
834 technology emerges. To help the reader, we use the abbreviations shown in Table 3 to indicate where
835 there are details related to a particular market formation process. For example, if the case refers to
836 ‘Demand articulation and empowerment function’, we include the abbreviation [*DemandArt*]. In
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 layer-
845 by-layer ‘printing’. 3D printing can be regarded as the interplay between printing technology, materials
846 to print with, and digital images to create a physical object. At its origin, 3D printing technology
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
849 associations (GARPA – the Global Alliance of Rapid Prototyping Associations²) and peer-reviewed
850 journals (e.g. Virtual and Physical Prototyping Journal, and the Rapid Prototyping Journal). The shift in
851 the use of 3D printing from rapid prototyping to direct manufacturing was driven by the maturation of
852 key technologies as well as the increasing availability of other materials for 3D printing, such as metals
853 and ceramics (Bak, 2003; Frazier, 2014). 3D printing enables circular, customized and decentralized
854 manufacturing and thus has the potential to stimulate green production (Despeisse et al., 2017).

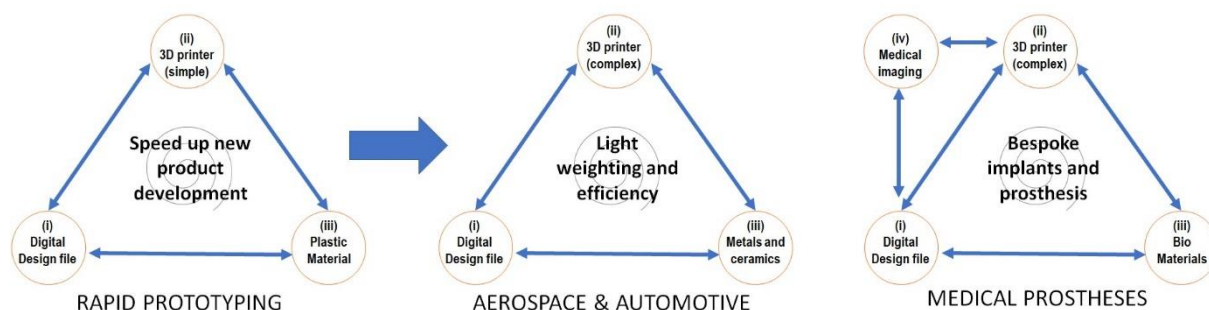
855 Professional users played a major role in co-developing 3D printing technologies for various niche
856 applications. A prominent example of one of the first application areas was the proposition of
857 customized one-off dental prostheses. Tooth prostheses were traditionally standardized, mass-produced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

862 In the late 1990s, dentists saw a potential market for using 3D printing to make patient-specific models
863 and surgical guides to plan and assist procedures (Gibson et al., 2006; Liu et al., 2006; Winder & Bibb,
864 2005). During this period of time, and because of the variety of demonstrations, dentists became
865 increasingly interested in mass customization, and proposed various requirements in terms of consumer
866 needs, technical standards and quality assurance. Custom implant and dental diagnosis was also being
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
870 contoured before it was attached to the mandibular angle with titanium screws” (Liu et al. 2006, p. 333)
871 [*DemandArt*].

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

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

875 in order to develop additive manufacturing capabilities. One such companies was Materialise (Belgium),
 876 which developed a software system (the Materialise Mimics™ software³) to translate medical imaging
 877 data into a 3D system, thereby enabling the design of dental prosthetics (Liu et al., 2006). Such support
 878 systems were essential to enable 3D printing to be effectively used for medical applications. The advent
 879 of printing with metal rather than plastic, particularly the cobalt-chrome that meets the high-quality
 880 standards of dentistry, made direct manufacturing of dental prostheses possible. De facto dominant
 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
 884 broadened the usual practice of dental prostheses design, production and fitting, enabling dentists
 885 themselves to customize prostheses, like orthodontic models, splints and dentures, and have them
 886 available at a much quicker rate [*NewUse*]. This market was delineated from other 3D printing markets
 887 by the development of tailored software for designing implants, and the adaptation of 3D printers to use
 888 biocompatible materials, such as cobalt-chrome, by drawing on dentistry standards. Firms such as
 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
 891 straddled multiple markets (for example fashion, aerospace and medical prostheses⁴), advancing
 892 technical standards for the printers across markets, while simultaneously tailoring their products and
 893 business development accordingly. There was also a cognitive aspect to this delineation of the market,
 894 as dentists advocated tailor-made products as the optimal standard, a move which requires surgeon-
 895 designers to be responsible for the creative and skills-based part of the manufacturing process (Dawood
 896 et al., 2015)[*MrktBndry*]. For example, dentists such as Dr. Michael Scherer claimed that “innovation
 897 within intraoral optical scanning and 3-D printing should continue to allow clinicians to make complex
 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.

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

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

⁴ <https://www.materialise.com/en/industries> (accessed 15/12/2021)

910 of national standard bodies (i.e. NIST), professional societies (i.e. SME), multinational corporations (i.e.
911 BMW, Siemens, Stryker & Honeywell), small and medium-sized firms, research universities as well as
912 federal agencies and research institutes (i.e. NASA, Naval Air Warfare Center, Air Force Research
913 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*].

916 At the same time, niche-specific institutions were introduced. Dental and other medical 3D printing
917 require medically approved materials of a standardized quality and sufficient evidence on safety to
918 support this, so that clinicians and insurance companies can make valid risk assessments. For example,
919 the US Food and Drug Administration⁵ started approving the use of digital patient scans in combination
920 with software and a 3D printer in 2013 to produce patient-matched denture teeth by depositing layer
921 upon layer of resin material (Molitch-Hou, 2013) [*InstiTrans*].

922 Case 2: Direct-to-consumer genetic testing

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
929 human genome sequencing to US\$1000" (Heather & Chain, 2016; van Dijk et al., 2014) [*DemandArt*].
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).

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

939 Genetic testing was soon to break out of the clinical context. Cheaper and faster tests sparked the
940 emergence of companies that began to explore the possibilities of offering genetic tests directly to
941 consumers, with or without the involvement of medical professionals. Two waves of direct-to-consumer
942 genetic testing companies have since surfaced (Hogarth & Saukko, 2017). The first wave concerned
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
946 2007 onwards and consisted of companies that began making use of next-generation sequencing
947 technologies, enabling polygenic risk tests for common diseases [*DomDesign*]. A direct-to-consumer
948 genetic testing sector emerged, which consisted of around 250 firms by 2016 (Phillips, 2016) featuring
949 companies like 23andMe as flagships.

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

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

952 health” (interview result). This empowerment of individuals tied in with using direct-to-consumer
953 predisposition tests for common diseases without clinical oversight [*DemandArt*]. At the same time, our
954 interviews and workshops revealed that clinicians might still be involved considering that the outcomes
955 of genetic tests would lead consumers to general practitioner’s offices for explanation, treatment or
956 consolation, increasing the burden on healthcare systems (Boon et al., 2015). A new ‘workflow’ arose
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
960 [*NewUse*]. Companies like from e.g. Navigenics or 23andMe approached customers, emphasizing the
961 narrative of creating social bonds or exchanging gifts (Harris et al., 2013) [*DemandArt*].

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
965 decisions. These tests became standardized [*DomDesign*], cheap and widespread and, in many
966 countries, sold and used under the guidance of medical specialists or pharmacists. Companies boosted
967 expectations of polygenic risk tests that look for combinations of susceptibility alleles that are associated
968 with a disease and can be used to predict whether an individual will develop it in the future [*DemandArt*].
969 The FDA and medical professionals question the predictive accuracy of such tests. They call for
970 “sufficient clinical validity” [*DemandArt*] and for complementing genetic testing with professional
971 counseling [*NewUse*].

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

984 23andMe and other commercial genetic testing companies survived by diversifying into and creating
985 new (sub-)markets [*MrktBndry*]. Most closely related to healthcare is the wellness market, in which
986 advice on nutrition and exercise, for example, can be based on genetic traits. Companies such as Helix
987 advertised the application of such tests to those particularly interested in a healthy lifestyle and sports,
988 e.g. related to “muscle composition”. Another market was formed for people wanting to know more
989 about their ancestry, familial proximity, talents and character. Here, companies like Ancestry anticipated
990 consumers’ growing interest in identity and race, which has been reinforced through popular culture and
991 social media (Marcon et al., 2021) [*DemandArt*]. By focusing on lifestyle and ancestry, the companies
992 were able to distance themselves from making health claims, which made clinical evidence and
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
997 (Mihalas et al., 2014). eHealth innovations are associated with the promise of contributing to the
998 transition towards preventive healthcare (Alonso et al., 2019). A wide variety of eHealth solutions, like
999 exercise apps for wearables and web portals for remote medical consults have been created and tested
1000 across the Netherlands and beyond, indicating that a dominant design has not yet 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
1004 healthcare organizations or with patients. They base their idea on their experiences as medical
1005 professionals or as IT specialists seeing business opportunities in healthcare. In the majority of cases,
1006 the idea behind an eHealth innovation concerns tracking health-related indicators and monitoring body
1007 functions to prevent diseases developing [*DemandArt*]. Companies also propose eHealth solutions as a
1008 way to make processes in healthcare organizations or patient-doctor interactions “richer and more
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
1016 lack of data standardization, interoperability problems, local health insurance regulations, privacy
1017 issues, and evidence of use in real-life contexts, among other reasons (Parente, 2000). As a result, such
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*].

1024 According to our respondents, the most prominent barrier to scale is that the regulations for
1025 reimbursement must be organized differently to enable not only supplementary but also substitution of
1026 physical therapy with the digital platform [*InstiTrans*]. Health insurers do not yet reimburse this, which
1027 is partly due to the conditions set by the government as well as the way in which the professional
1028 association defines good clinical practice [*NewUse*].

1029 Despite difficulties in scaling, there seem to be three established ‘exit routes’ that we distinguished in
1030 the innovation projects we studied: direct-to-consumer (e.g. measuring personal health through simple
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
1034 own rationale: direct-to-consumer focuses on health-conscious consumers, whereas doctor-mediated
1035 and platform-based eHealth products are often part of established diagnostic and therapeutic workflows
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
1038 integrated into the standard care and guidelines of medical professional associations to become eligible
1039 for health insurance reimbursement. Inclusion in such guidelines requires gathering data on efficacy and

1040 safety [*InstiTrans*]. Companies struggling with legislation and regulations sometimes try to change these
1041 rules and norms, especially when medical professional associations have vested interests in not
1042 including eHealth products in their guidelines and may have an “inhibitory effect” [*InstiTrans*].

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

1044 We are interested in diagnosing misalignments, bottlenecks and failures when technology-based markets
1045 emerge in the context of transitions. Based on the three described cases (see Appendix A, Table A.1 for
1046 a comparison of cases with the market formation functions), we answer three questions to explore to
1047 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
1049 to distinct issues about emerging markets. The ‘Demand articulation and empowerment’ process shows
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
1055 predefine how workflows should be organized (genetic testing). In the context of ‘Formation of
1056 institutions and institutional entrepreneurship’, all three cases show companies fighting the vested
1057 interests of incumbent companies or professions. Companies are mostly involved in pro-actively
1058 ‘Defining legitimate market boundaries and establishing dominant product categories’ as a way to create
1059 moral support and legitimacy. The three cases show the definition of new ‘exit routes’ (eHealth) or
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.

1066 Whether the set of five processes is comprehensive enough is difficult to tell, because there might be
1067 ‘unknown unknowns’. However, although the methodological approach always included open questions
1068 that could have gone beyond the five processes, in no case did we find aspects of market formation that
1069 were not covered by the five processes. At the very least, we can say that the processes in combination
1070 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.

1079 To go one step further, not only do the activities related to the processes interact, they seem to do so in
1080 a certain order, underlining the dynamic character of emerging markets. For example, all three cases had
1081 to deal with strict regulations and norms invested in by incumbent companies and professions. Re-
1082 articulating preferences and expectations, experimenting and developing workflows and practices, and

1083 diverging and (re)defining markets led to either incorporation or circumventing existing institutions.
1084 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
1089 practice beyond certain pilots (eHealth), difficulty in re-orientation of the profession (3D printing;
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.

1097 Based on the explorative comparison, we close by discussing the market formation functions and their
1098 use in a functional framework for characterizing and analyzing different processes of new market
1099 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
1109 intertwined questions. Questions for further research would be whether the list of market formation
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).

1114 Second, the cases indicate patterns of events underlying the market formation processes in emerging
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
1117 up work on the timing of policy interventions for market formation. Importantly, there is no natural
1118 order or linear stage model implied by the five processes, neither is there a dominant process that serves
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
1121 demand-side institutions like professionals, norms and reimbursement criteria are hindering the
1122 formation of new markets, which requires increased efforts of demand articulation and the re-orientation
1123 of market boundaries. Such patterns seem to point to chains of events, reflected in the market formation
1124 processes, which reinforce themselves and lead to positive or negative outcomes. These functions
1125 interact and may form virtuous or vicious cycles and even ‘waiting games’ or Catch 22 situations

1126 (Robinson et al., 2012). It will be useful to study successful and unsuccessful market formation with the
1127 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
1132 acknowledging this has broader repercussions for transition studies, as transitions are an interplay of
1133 multiple, intertwined market formations, as in the case of the circular economy. The important lesson
1134 here is that markets are not isolated, institutional arrangements, but emerge in a context of rival or
1135 complementary production and use contexts (Schanz et al., 2019). Furthermore, the notion of markets
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
1142 and ancestry markets, and, as we have seen above, institutional pressures led companies to sidestep into
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
1145 applied the processes to three cases, the next step should be a more widespread application of the
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
1150 a key role in transformative change. To elaborate on this point, one could explore how the non-technical
1151 sources of innovation, such as social innovation and organizational innovation, may lead to new market
1152 formation, for example in relatively new markets such as the sharing economy, certified organic food
1153 markets and emissions trading. We suggest that the market formation processes developed and
1154 demonstrated in this paper will be useful for analyzing non-technology-based markets, however, we also
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
1159 are detrimental to the emergence of markets in transitions. Being able to pinpoint *misalignments*,
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 &
1165 Mazzucato, 2019) that necessitates a deeper understanding of market formation processes, and possible
1166 policy interventions. Even where markets seemed to emerge without any deliberate public policy
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
1170 push a societally desirable technology or to steer the market more generally in a socially desirable

1171 direction. This resonates with the calls to work on “anticipating and learning about user needs”, which
1172 Weber and Rohrer (2012) marked as ‘demand articulation failure’ in the context of tackling grand
1173 societal challenges, and on promoting demand-side innovation policy measures (Boon & Edler, 2018;
1174 Edler & Georghiou, 2007). In consequence, there is a need for a framework to trace market formation
1175 from early stages of technology emergence onwards and in real-time, to preconceive what these
1176 technologies mean for niche but also future mass markets.

1177 We can now turn to what our concept means for policy. A major role for transformative policy is to help
1178 reduce uncertainty for all market actors across all five functions, to create transparency, to support
1179 directionality, discourse and interaction, and to provide regulatory frameworks that are flexible enough
1180 to allow further adjustments in the formation process, but provide sufficient stability for potential
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
1184 dysfunctionalities of the market formation processes then present entry points for policy intervention.

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

1196 Potential directions for policy intervention to be developed follow from the five market formation
1197 processes. A slow innovation uptake can, for example, be caused by a *poor articulation of demand* in
1198 early stages, thus hampering the design of technological solutions that are much more in line with market
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
1205 be required to challenge users and enable them to learn. Further, new regulations may be needed to
1206 establish novel workflows. In this context, new technologies often raise concerns about what constitutes
1207 this new market, what the normative standards and the *legitimacy of market boundaries* are. Policy
1208 interventions here would have to focus on an open and transparent discourse about the concerns and
1209 hopes associated with technological innovations and the transition they support, leading to a higher level
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
1214 of which actors are entitled to which parts of the market. This necessitates regulatory clarifications on
1215 property rights and the rules of exchange, potentially accompanied by regulatory sandboxes to allow for
1216 the development of appropriate regulation. This is strongly related to the *establishment of dominant*

1217 *designs* that will shape the final market. Often, this happens through market forces alone in forming de
1218 facto standards. However, the state may intervene in order to speed up this process, influence the
1219 direction of standardization and ensure de facto standards are in line with the regulations that shape
1220 market formation as a result of the market formation discourse. The development and deployment of
1221 dominant designs can be pushed through public procurement. In the appendix, we illustrate the demand-
1222 side bottlenecks and possible policy interventions along our three cases. These illustrations show how
1223 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**

1226 Our approach to market formation is informed by complementary theoretical perspectives. By
1227 combining these perspectives in a functional framework covering five market formation processes, we
1228 are able to advance the study of market formation in the context of transformative policy. The
1229 advancements are in line with calls for taking a process perspective (Dewald and Truffer, 2012), for
1230 opening the black box of forming markets (Bergek et al., 2015) and especially elaborating on the
1231 demand-side of markets which is currently under-addressed in transformative innovation policy (Weber
1232 and Rohrer, 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
1236 major prerequisites for appropriate and legitimate policies to support demand and market formation.
1237 (Boon and Edler 2018, p. 439).

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

	<p>different user contexts, in protected spaces if needed. Policy: regulatory sandboxes and public demonstrators.</p>	<p>identify any regulatory issues early on to prevent misaligned technology been rolled out with negative market creation effects.</p>	<p>Policy: awareness raising initiatives, user training, demand subsidies to cover learning costs with users.</p>
<p><i>Formation of institutions and institutional entrepreneurship</i></p>	<p>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 regulatory bodies.</p>	<p>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.</p>	<p>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.</p>
<p><i>Defining legitimate market boundaries and establishing dominant product categories</i></p>	<p>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.</p>	<p>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.</p>	<p>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.</p>

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