Table 7 Incentive-compatibility analysis for SA-Q

ψ	Degree of exaggeration				
	Reference	75%	50%	25%	12.5%
2.8	0.9875	1.0061	–	–	–
3.1	0.9903	1.0107	–	–	–
4.0	0.9904	1.2708	1.4464	1.5071	–
4.3	0.9882	0.9662	1.0042	0.9727	0.9981
4.6	1.0015	1.0037	0.9858	0.9866	0.9974
5.9	1.0042	1.0107	1.0010	0.9840	1.0040

Table 8 Incentive-compatibility analysis for MWIS-Q

ψ	Degree of exaggeration				
	Reference	75%	50%	25%	12.5%
2.8	1.0022	0.9656	–	–	–
3.1	0.9783	0.9777	–	–	–
4.0	1.0035	1.0051	–	–	–
4.3	0.9763	1.1459	1.4785	1.3523	1.1614
4.6	0.9882	0.9463	0.9991	0.9672	0.9968
5.9	1.0091	1.0145	1.0054	0.9544	1.0139

gain is achieved for 50% degree of exaggeration, and further narrowing of the exaggerated bid set makes the gain for the insincere agent decrease, but it does not make negotiations fail. This is an effect of the higher correlation in the MWIS-Q selected scenario ($\psi = 4.3$), which makes deal probability higher. Finally, we can observe that exaggeration of the 75% of the bids has no significant effect, since most agent bids are included in the exaggerated set in this case. From these results we can conclude that there are incentives for the agents to behave insincerely in those scenarios, and therefore additional mechanisms should be introduced in the model to make it incentive-compatible.

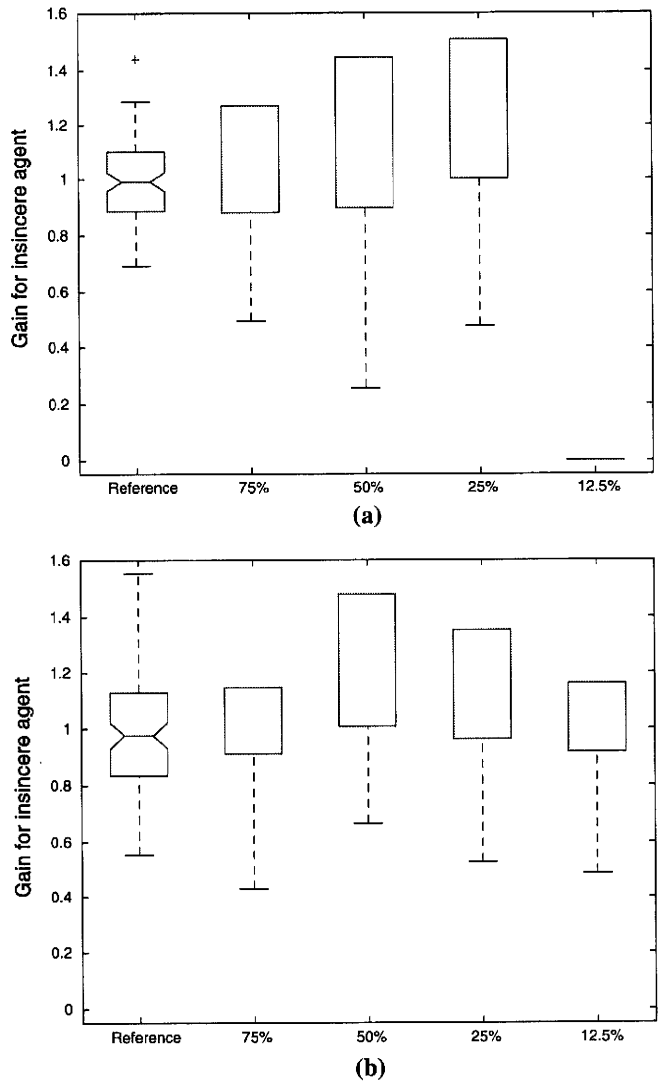
6.3 Incentivizing sincere behavior in the auction-based negotiation protocol

As we have seen, the proposed model is prone to manipulations by means of *exaggerations* made by the agents, and there is an incentive for agents to behave insincerely. This is an undesirable property in a negotiation model, and may lead to further stability problems. Therefore, we seek for mechanisms which counter this effect, incentivizing sincere revelation of information. A possibility to achieve this is to normalize the utility values assigned by the agents to their bids, thus lowering the absolute differences in utility. We propose three different possibilities regarding utility normalization:

- *Normalization to maximum utility* : obtained by dividing each agent's bid utility by the maximum utility value issued by that agent:

$$u_n(b_i) = \frac{u(b_i)}{\max_{b_j \in B} u(b_j)}. \tag{6}$$

  Using this normalization mechanism we can avoid the manipulation of the final deal by exaggerating upwards the utility values of the preferred offers. It does not prevent,



(a)

(b)

Fig. 12 Detail of the incentive-compatibility analysis for the most critical scenarios. **a** SA-Q $\psi = 4.0$, **b** MWIS-Q $\psi = 4.3$

however, downward exaggerations, that is, to assign an extremely low value to the bids which are less profitable for the agent.

- *Bounded maximum-minimum normalization*: Attempts to prevent the manipulation of the negotiation model through upwards or backwards exaggerations. It is given by the expression

$$u_n(b_i) = u'_{\min} + \frac{u(b_i) - u_{\min}}{u_{\max} - u_{\min}} \left(u'_{\max} - u'_{\min}\right), \qquad (7)$$

where $u_{\max} = \max_{b_j \in B} u\left(b_j\right)$, $u_{\min} = \min_{b_j \in B} u\left(b_j\right)$ and $u'_{\min}$ and $u'_{\max}$ are parameters chosen by the mediator. In this way, a utility mapping from the interval $[u_{\min}, u_{\max}]$ to the interval $\left[u'_{\min}, u'_{\max}\right]$ is performed for all bids, putting an upper bound $\frac{u'_{\max}}{u'_{\min}}$ to the ratio between the utilities of an agent's bids.

- *Ordinal normalization:* obtained by ordering the different bids of an agent according to their utility or quality factor, and mapping this order to a monotonically increasing succession of utility values, regardless of the original utility values. For instance, if B is the set of bids for an agent, in ascendent order of utility, and taking the arithmetic succession $s = \{1, 2, \ldots, n_B\}$ as the mapping function, the normalized bid utility values would be of the form

$$u_n\left(b_i\right) = s_i = i.$$

Our hypothesis is that using these normalization methods may positively contribute to the incentive-compatibility of the model. To evaluate the effect of the proposed mechanisms over the incentive-compatibility of the model we have repeated the experiments performed above for the different normalization mechanisms proposed:

1. *Reference:* Utility values are not normalized.
2. *Umax:* Mediator uses *normalization to maximum utility* (Eq. 6).
3. *Bounded:* Mediator uses *bounded maximum-minimum normalization* (Eq. 7).
4. *Ordinal:* Mediator uses *ordinal normalization.*

Figure 13 a and b show the box plots of the results for 100 runs of the experiments for SA-Q and MWIS-Q in the most critical scenarios identified above, that is, $\psi = 4.0$ with a 25% degree of exaggeration for SA-Q and $\psi = 4.0$ with a 50% degree of exaggeration for SA-Q. We can see similar trends for both cases. Though all proposed normalization techniques reduce the incentive for the insincere agent to exaggerate, only bounded maximum-minimum normalization makes the expected gain for the insincere agent negligible, thus effectively removing the incentive to exaggerate, improving incentive-compatibility of the model.

7 Concluding remarks

Situations of high price of anarchy, which imply that individual rationality drives the agents towards strategies which yield low individual and social welfares, should be avoided when designing negotiation mechanisms. This is specially important when dealing with complex negotiations involving highly rugged utility spaces, since in these cases "low individual and social welfare" often means that the negotiations fail. Therefore, an strategic analysis is paramount for any model intended to work for highly rugged utility spaces, in order to determine the strategic properties of the model and to allow to establish additional mechanisms for stability if needed.

In this paper we have performed a strategy analysis for the auction based negotiation protocol for highly rugged utility spaces we proposed in refs. [31,55]. This strategy analysis has started studying the existence of individual and social optimal strategy profiles. This has revealed the existence of an individual optimal strategy, which is different from the socially optimal strategy. A more in-depth stability analysis has shown that, for highly correlated or lowly correlated scenarios, there is no incentive for negotiating agents to deviate from the socially optimal strategy. However, for medium complexity scenarios a selfish agent may

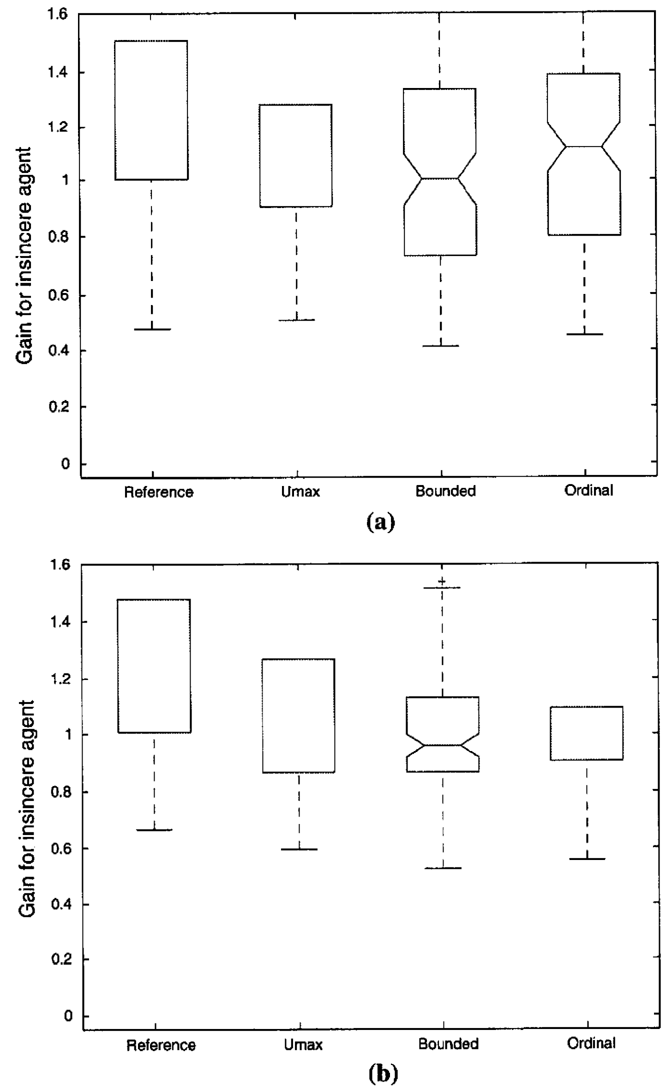


Fig. 13 Effect of the proposed normalization mechanisms for the most critical scenarios. **a** SA-Q, $\psi = 4.0$, 25% degree of exaggeration. **b** MWIS-Q, $\psi = 4.3$, 50% degree of exaggeration

benefit from using its individually optimal strategy, which raises stability concerns, leading the model to high expected price of anarchy values. To solve this, we have proposed a set of mechanisms intended to incentivize social behavior among negotiating agents. These mechanisms are based on biasing deal identification at the mediator towards those bids which are more socially oriented, thus decoupling the search for social welfare from the individual agents' goals. Experiments show that the proposed mechanisms successfully stabilize the protocol, avoiding the situations of infinite expected price of anarchy.

Finally, incentive compatibility issues in the protocol have been analyzed, showing that the model may be manipulated by agents which exaggerate the utility values of a subset of their bids, achieving significant gains for the insincere agents in medium correlated scenarios. To solve this, a set of normalization techniques have been proposed in order to incentivize sincere behavior. Experiments have shown that, though all proposed techniques reduce the incentive for an agent to exaggerate its bids, only the proposed bounded maximum-minimum normalization mechanism effectively removes the expected gain for being insincere, thus making the model incentive-compatible.

Though the experimental analysis performed has proven the effectiveness of the stability and incentive-compatibility mechanisms proposed, there is still plenty of research to be done in this area. We are interested on extending the strategy analysis presented in this work to an iterative version of the studied negotiation protocol, which would allow the agents to refine their bids in successive iterations of the protocol. This would raise very interesting additional considerations regarding agent and mediator strategies, since it would allow to develop adaptive measures. For the negotiation agents, this would mean, for instance, to be able to acquire a reasonable belief about the other agents' strategies during the negotiation, and to adapt its own strategy accordingly. This would drastically change the strategy analysis, since it would have to be conducted in a similar manner to a Bayes-Nash problem. The different results of the strategy analysis would probably impact the mechanisms needed at the mediator, and even more taking into account that the mediator could also take advantage of adaptive measures, trying to deduce agent strategies during the negotiation process, and to apply the different mechanisms as needed. In addition, the effect of the correlation between the utility functions of *different* agents (as opposed to the correlation length within each agent's utility function) should be analyzed. Finally, we are working on the generalization of these approaches for other negotiation protocols and utility function types.

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A Appendix: Deduction of the expressions used in the probabilistic analysis

This section deduces these expression used in Sect. 4.1 for the probabilistic analysis of the auction based negotiation model. For ease of understanding, the deduction of the expressions is presented in a progressive manner. First of all, deal probability is calculated for an exchange between two agents of an *elemental* bid (a single unitary bid for each agent, for a single issue), and then it is shown how the expression varies when the number of issues and agents increase. Then, the resulting expression is generalized for an arbitrary number of bids per agent. Finally, given the expression for deal probability, expressions for expected utility and expected deal utility (defined as the expected utility conditioned to the event of a successful deal) are determined.

A.1 Deal probability

Considering the negotiation protocol described in Sect. 3.2, the probability of finding a deal is given by the probability of finding a common intersection of at least one bid of each agent. The simplest scenario we can devise is a bilateral, single issue negotiation where each agent makes a single, elemental bid, that is, a bid that represents a single point in the solution space.

Let a y b be the negotiating agents, and let $x^a, x^b \in D$ be their respective offers in a finite domain D with cardinality $|D|$. The probability P_{solution} of a deal or solution to the negotiation problem in this case is given by the probability of the coincidence of both bids. In this way,

$$\begin{aligned} P_{solution} &= \bigcup_{x \in D} p\left[(x^a = x) \cap \left(x^b = x\right)\right] = \underbrace{\sum_{x \in D} p\left[(x^a = x) \cap \left(x^b = x\right)\right]}_{x^j = x \text{events are disjoint}} \\ &= \underbrace{\sum_{x \in D} p\left(x^a = x\right) p\left(x^b = x\right)}_{x^a \text{ and } x^b \text{ are independent}} = \sum_{x \in D} \frac{1}{|D|} \frac{1}{|D|} = \frac{|D|}{|D|^2} = \frac{1}{|D|}, \end{aligned} \tag{8}$$

where we have assumed as the probability that a bid has a given value $p\left(x^a = x\right) = \frac{1}{|D|}$, which corresponds to a uniform bid distribution, for a maximum uncertainty scenario.

Extending the previous expression to a bilateral negotiation about n issues is straightforward. Again, let us consider the simplest case of a single elemental bid per agent. In this case, each bid will represent a point in an n-dimensional solution space, and the deal probability will be given by the probability of *all* issue values corresponding to one agent's bid matching the respective values of the issues corresponding to the other agent's bid.

Let a y b be the negotiating agents, and let $x^a, x^b \in D$ be their respective offers, such that the bid issued by agent j is given by $\bar{x}^j = \left\{x_i^j \mid i \in 1, \dots, n\right\}$, and such that $x_i^j \in D \; \forall i, j$. The probability of a deal or solution to the negotiation problem in this case is given by the expression

$$\begin{aligned} P_{solution} &= \bigcap_{1 \leq i \leq n} \left\{ \bigcup_{x \in D} p\left[\left(x_i^a = x\right) \cap \left(x_i^b = x\right)\right] \right\} \\ &= \underbrace{\prod_{1 \leq i \leq n} \left\{ \bigcup_{x \in D} p\left[\left(x_i^a = x\right) \cap \left(x_i^b = x\right)\right] \right\}}_{\text{issue matches are independent events}} = \prod_{1 \leq i \leq n} \frac{1}{|D|} = \frac{1}{|D|^n}. \end{aligned} \tag{9}$$

In a similar way, this expression may be generalized to the case of n_a agents, taking into account that deal probability in this case is given by the probability of a match between the respective values for *all* issues of *all* agents' bids, and that each agent bid is independent from the others'. In this way, the expression for the probability of finding a solution or deal in this case will be the following:

$$\begin{aligned} P_{solution} &= \bigcap_{1 \leq i \leq n} \left\{ \bigcup_{x \in D} p \left[\bigcap_{1 \leq j \leq n_a} \left(x_i^j = x\right) \right] \right\} \\ &= \bigcap_{1 \leq i \leq n} \left\{ \bigcup_{x \in D} \left[\prod_{1 \leq j \leq n_a} p\left(x_i^j = x\right) \right] \right\} \\ &= \bigcap_{1 \leq i \leq n} \left\{ \sum_{x \in D} \left[\prod_{1 \leq j \leq n_a} p\left(x_i^j = x\right) \right] \right\} \end{aligned}$$

$$
\begin{aligned}
&= \bigcap_{1\le i\le n} \left\{ \sum_{x\in D} \left[\prod_{1\le j\le n_a} \frac{1}{|D|} \right] \right\} \\
&= \bigcap_{1\le i\le n} \left\{ \frac{|D|}{|D|^{n^a}} \right\} = \prod_{1\le i\le n} \left\{ \frac{1}{|D|^{n_a-1}} \right\} \\
&= \frac{1}{|D|^{n(n^a-1)}}. \qquad (10)
\end{aligned}
$$

So far we have considered only single, elemental bids, that is, each agent issued a single bid representing a single point in the solution space. This assumption allowed us to ensure deal events were disjoint (there was only a possible deal), which allowed to compute probabilistic unions as sums of probabilities. Generalizing to the case of multiple bids makes multiple points of agreement possible, and thus makes necessary to take into account possible intersection among deal events to compute probabilistic unions.

Given a set of N events $E_1, \ldots, E_N$, with known probabilities $p(E_i)$, and not necessarily disjoint, the probability of the union $\bigcup_{i=1}^{N} E_i$ is given by

$$
p\left(\bigcup_{i=1}^{N} E_i\right) = 1 - p\left(\bigcap_{j=1}^{N} \overline{E_i}\right).
$$

If the events are independent and equiprobable, we have that $p(E_i) = p$, $p\left(\overline{E_i}\right) = 1 - p$, and the probability of the intersection above is given by $p\left(\bigcap_N \overline{E_i}\right) = (1-p)^N$. In this case, we can see that the above expression leads to the following:

$$
\begin{aligned}
p\left(\bigcup_{i=1}^{N} E_i\right) &= 1 - (1-p)^N \\
&= 1 - \sum_{j=0}^{N} \binom{N}{j} 1^{N-j} (-p)^j \\
&= 1 - \sum_{j=0}^{N} \binom{N}{j} (-1)^j p^j \\
&= \sum_{j=1}^{N} (-1)^{j+1} \binom{N}{j} p^j. \qquad (11)
\end{aligned}
$$

This result can be used to generalize the expression for deal probability obtained in the previous section to the case of multiple offers. Let us consider again a set of n_a agents negotiating about n issues. In this case we will consider that each agent k sends n_{bp}^k elemental bids. We consider elemental bids without loss of generality, since any other kind of bids (e.g. hyper-rectangles) can be decomposed to elemental bids. There may be overlaps between the different bids of an agent (i.e. they may or may not be disjoint). The probability P_{solution} that there is a solution or deal to the negotiation problem will be given by the probability that *at least one* of the possible combinations of bids from the different agents results in a deal. If each agent k issues n_{bp}^k bids there are $\prod n_{bp}^k$ possible combinations of one offer of each agent. The event C_l denotes the fact that the combination l results in a deal. The different events C_l

are equiprobable, and their probability is given by Eq. 10, reproduced here for convenience:

$$p\left(C_l\right) = \frac{1}{|D|^{n(n^a-1)}}.$$

Taking this into account, and using Eq. 11 for the computation of the probability of a union of equiprobable events, deal probability for the set of bids is given by the expression

$$\begin{aligned} P_{\text{solution}} &= p\left(\bigcup_{l=1}^{\prod n_{bp}^k} C_l\right) = \sum_{j=1}^{\prod n_{bp}^k} (-1)^{j+1} \binom{\prod n_{bp}^k}{j} p\left(C_l\right)^j \\ &= \sum_{j=1}^{\prod n_{bp}^k} (-1)^{j+1} \binom{\prod n_{bp}^k}{j} \left(\frac{1}{|D|^{n(n^a-1)}}\right)^j. \end{aligned} \tag{12}$$

A.2 Expected utility and expected deal utility

Once deal probability has been determined, it is easy to compute expected utility. By definition, the expected value of a random variable X which takes values from a domain D is computed as the sum $\sum_{x\in D} x \cdot p\left(X = x\right)$ of the products of each possible value for the variable and the respective probability that the variable takes each value. For the case of the expected utility for an agent, the possible values of the variable are the utility values associated to the different bids, and the probability that the variable takes each value is the probability that each bid results in a deal. To compute this probability, we have to take into account that each elemental bid $\bar{x}_i^j$ of an agent j may be part of $\prod_{k\neq j} n_{bp}^k$ events $C\left(\bar{x}_i^j\right)_l$, representing the fact that the different combinations of this bid with the different elemental bids of the rest of the agents may result in a deal. In this way, the deal probability for a given elemental bid $\bar{x}_i^j$ is given by

$$p\left(\bar{x}_i^j\right) = p\left(\bigcup_{l=1}^{\prod_{k\neq j} n_{bp}^k} C\left(\bar{x}_i^j\right)_l\right) = \sum_{j=1}^{\prod_{k\neq j} n_{bp}^k} (-1)^{j+1} \binom{\prod_{k\neq j} n_{bp}^k}{j} \left(\frac{1}{|D|^{n(n^a-1)}}\right)^j.$$

From this expression, the expected utility for an agent j is computed as follows:

$$\begin{aligned} E\left[u^j\right] &= \sum_{i=1}^{n_{bp}^j} u\left(\bar{x}_i^j\right) p\left(\bar{x}_i^j\right) \\ &= \sum_{i=1}^{n_{bp}^j} \left[u\left(\bar{x}_i^j\right) \sum_{j=1}^{\prod_{k\neq j} n_{bp}^k} (-1)^{j+1} \binom{\prod_{k\neq j} n_{bp}^k}{j} \left(\frac{1}{|D|^{n(n^a-1)}}\right)^j \right] \\ &= \left[\sum_{i=1}^{n_{bp}^j} u\left(\bar{x}_i^j\right)\right] \left[\sum_{j=1}^{\prod_{k\neq j} n_{bp}^k} (-1)^{j+1} \binom{\prod_{k\neq j} n_{bp}^k}{j} \left(\frac{1}{|D|^{n(n^a-1)}}\right)^j\right], \end{aligned} \tag{13}$$

where $\sum_{i=1}^{n_{bp}^j} u\left(\bar{x}_i^j\right)$ is the sum of the utilities of all points issued as bids by the agent. For the case of non-elemental bids, we consider each agent j issues n_b^j bids. Each bid m of the agent represents an *iso-surface* of the agent's preference space (e.g, an hyperrectangle), and thus may be decomposed in v_m^j elemental bids of the same utility u_m^j, where v_m^j is the *volume* of the iso-surface represented by the bid m. In this case, we can establish the equivalence $\sum_{i=1}^{n_{bp}^j} u\left(\bar{x}_i^j\right) = \sum_{m=1}^{n_b^k} u_m^k \cdot v_m^k$, and the expression for the expected utility results as follows

$$E\left[u^j\right] = \left[\sum_{m=1}^{n_b^k} u_m^k \cdot v_m^k\right] \left[\sum_{j=1}^{\prod_{k \neq j} n_{bp}^k} (-1)^{j+1} \binom{\prod_{k \neq j} n_{bp}^k}{j} \left(\frac{1}{|D|^{n(n^a-1)}}\right)^j\right],$$

which is the expression we saw for Eq. 2.

Finally, expected deal utility for an agent may be obtained easily, since it only depends on the utility distribution within the set of bids issued by the agent. Assuming a deal have been reached, the probability for each elemental bid to be part of the deal will be $p\left(\bar{x}_i^j \,|deal\right) = \frac{1}{n_{bp}^j}$, assuming the different elemental bids are equiprobable (maximum uncertainty scenario). Taking this into account, expected deal utility is given by

$$E[u^j \,|deal] = \sum_{i=1}^{n_{bp}^j} u\left(\bar{x}_i^j\right) p\left(\bar{x}_i^j \,|\text{deal}\right) = \frac{1}{n_{bp}^j} \sum_{i=1}^{n_{bp}^j} u\left(\bar{x}_i^j\right),$$

which, for hyperrectangular bids, takes the form we saw in Eq. 3:

$$E[u^j \,|deal] = \frac{\sum_{m=1}^{n_b^j} u_m^j \cdot v_m^j}{n_{bp}^j}. \tag{14}$$

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第9章

医療機器と医薬品に関連する製造物責任*

佐藤智晶

1　はじめに

本章で扱う問題は，製造物責任のなかでも近年注目を集めている医療機器と医薬品に関連するものである．医療機器と医薬品産業が発展しているアメリカでは，製品の安全性を確保するための製造物責任法と公法的な規制の役割分担をめぐる研究が活況を呈している．そのような研究は，わが国で革新的な医薬品・医療機器を創出し，より多くの患者を救うためにも有益と考えられる．

近年，わが国では医薬品と医療機器産業の発展に対する期待が高まっている1)．例えば，2007年には4省（内閣府，文部科学省，厚生労働省，経済産業省）合同で「革新的医薬品・医療機器創出のための5ヵ年戦略」が公表された2)．この5ヵ年戦略は，わが国の優れた研究開発力をもとにして，世界最高水準の革新的医薬品・医療機器の創出，世界市場におけるわが国発の製品シェアの拡大，そしてそれらを国民に迅速に提供することを目標とする政策パッケージである．このような政策パッケージは，わが国における医薬品と医療機器産業の発展に対する高い期待の現れといえよう．

ところが，医療機器と医薬品をめぐっては，研究開発コストが飛躍的に増大しており，各国の国際競争が激化している3)．また，少なくとも医療機器産業についていえば，新規参入と部材供給が十分に進んでいないという問題がある．

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1）例えば，林良造「経済教室：イノベーション医療を軸に」日本経済新聞2007年3月9日付朝刊を参照．

2）革新的創薬等のための官民対話「革新的医薬品・医療機器創出のための5か年戦略（改定）」(2009年2月12日)．

世界第2位の医療機器市場を有しているにもかかわらず，わが国では医療機器分野への新規参入が十分に活性化されているとは言い難く，もともとの産業基盤の強みが生かされていない．例えば，国内市場に占める輸入比率は年々増加し，平成7年の35.5%から，平成18年には48.6%まで上昇しており，治療機器市場では，特にその傾向が顕著である[4]．

医療機器分野への参入・部材供給が進まない原因は明らかになっていないものの，これまでに製造物責任や規制などが指摘されている．例えば，2008年3月に公表された財団法人化学技術戦略推進機構の報告書によれば，「部材供給に意欲ある中小企業が現に存在するが，供給して万一問題が起きた場合には企業規模を越えた賠償責務を負うのではないかとの不安のため，供給決断ができないでいる」という[5]．また，規制については，薬事法などの規制関連コストや審査・承認までに時間がかかることから，企業が製品の導入に消極的になっているという調査結果がある[6]．

これまで，わが国では製造物責任の問題はもちろん，公法的な規制である審査・承認手続きと訴訟との間の相互作用については，十分に検討されてこなかった．まず，製造物責任法の研究は，立法後ほとんど進んでいない．わが国では，被害者の円滑かつ適切な救済を図るために製造物責任法が施行されて14年になるが，同法に基づく訴訟はわずか109件にとどまる[7]．そのためもあり，近年，この分野の法学研究は盛んとはいえない．とりわけ，製造物責任について多くの裁判例があるアメリカ法研究の状況は寂しいという他ない[8]．

他方，審査・承認手続きの問題については，すでに詳細な研究が行われてい

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3) 医療機器については，経済産業省商務情報政策局医療・福祉機器産業室「医療機器分野への参入・部材供給の活性化に向けた研究会　開催趣旨」（平成20年3月31日）を，医薬品については，経済産業省製造産業局生物化学産業課「バイオイノベーション研究会について」（平成21年11月16日）を参照．

4) 以上については，経済産業省・商務情報政策局医療・福祉機器産業室「平成20年度医療機器分野への参入・部材供給の活性化に向けた研究会中間報告書」（2009年7月）4頁を参照．

5) 財団法人化学技術戦略推進機構「先端的医療機器事業への挑戦を促す社会基盤の構築と整備に向けて」（2008年3月）7頁．

6) 在日米国商工会議所医療機器・IVD小委員会「2008年デバイスラグ調査」（2008年10月）6，17-20頁．関連データとして，三菱総合研究所「医療機器のコスト構造に関する国際比較調査」（2009年7月）23-26頁．

7) 国民生活センター「製品関連事故に係る消費生活相談と製造物責任法に基づく訴訟の動向」（2008年10月23日）1頁．

るものの[9]，訴訟との間の相互作用についてはほとんど関心が持たれていない．すなわち，適正な審査・承認・手続を経て販売されている医療機器と医薬品について，製造物責任法がどのように適用されるのか，そしてメーカーは，どのような要件を満たせば免責されるのかが，十分に明らかにされていないということである．

以上を踏まえて，本章ではアメリカにおける医療機器と医薬品に関連する製造物責任の問題を取り上げつつ，わが国において革新的な医療機器と医薬品の開発を活性化させる一方，国民の安全を確保するための基礎的な比較検討を行う．

以下では，医療機器と医薬品に関連する製造物責任の特徴を説明し，まず医療機器に関する製造物責任を分析する．次に，アメリカの裁判所において医療機器とは異なる扱いを受けている，医薬品に関する製造物責任を分析する．そして最後に，わが国において革新的な医療機器と医薬品の開発を活性化させ，危険な製品から患者を守るための示唆をまとめる．

2　医療機器と医薬品に関連する製造物責任の特徴

医療機器と医薬品の製造物責任は，他の一般的な製品と決定的に異なる特徴を持っている．そのなかで最も顕著な違いの1つに，不合理な危険性を持つ製品から患者を守る医師の役割がある．すなわち，一般的な製品の場合には，製造業者が最終消費者に製品の危険性について十分に警告すべきところ，処方薬と医療機器の場合には，製薬会社や医療機器メーカーが，患者ではなく医師に警告すべきものと解されている．以下，アメリカの製造物責任について簡単に説明してから，医療機器と医薬品に関連する製造物責任の特徴をまとめる．

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8) 例えば，平野晋『アメリカ製造物責任法の新展開——無過失責任の死』(成文堂，1995)，ジェリー・J・フィリップス（内藤篤訳）『アメリカ製造物責任法』(木鐸社，1995)，小林秀之『製造物責任法』(サイエンス社，1995)，中村弘『製造物責任の基礎的研究』(同文舘，1995)，アメリカ法律協会(森島昭夫監修・山口正久訳『米国第3次不法行為法リステイントメント製造物責任法』(木鐸社，2001)，朝見行弘「海外の製造物責任法制の動向」Law & Technology 42号 (2009) 27頁．

9) 一例として，財団法人機械システム振興協会『高質な国民生活をもたらす先端医療機器技術の社会的導入方策に関する調査研究』(2007)．

2.1　アメリカの製造物責任法

アメリカの製造物責任法は，わが国の製造物責任法と同じように製造業者に製品の安全性を向上させ，事故を防止する誘因を与えるための法である．製造物責任法は，連邦法の規制とは明らかに性質が異なる．第1に，製造物責任法は，連邦の制定法ではなく州の判例法を主な法源とする．

第2に，製造物責任法では，数多くの訴訟を通じて製造業者の義務が徐々に明らかになる．他方，連邦法の規制では，制定法や行政規則によって製造業者の義務が事前に具体的に明らかにされていて，規制は事故前から開始されている．

第3に，製造物責任法では被害者の救済が図られる．製造物責任は，欠陥製品を販売したメーカーに被害者の損害を填補させることによって，メーカーに事故の発生を防止する誘因を与える10)．他方，連邦法の規制には，このようなメーカーから被害者への富の再配分機能はない．

以上のように，アメリカにおける製造物責任法は，製造販売業者が最終消費者に負う義務に関係する州の判例法で，不合理な危険性を持つ製品を販売して消費者を負傷させたメーカーに損害賠償責任を負わせるものである．では，医療機器と医薬品は，他の一般的な製品とどこが異なるのか．それは，連邦法の規制を受けるのはもちろんのこと，メーカーだけでなく医師が最終消費者の安全のために関与している点である．

2.2　医療機器と医薬品という製品の特徴

医療機器と医薬品は，連邦法の規制を受けている製品の1つである．例えば，医療機器と医薬品は，アメリカでは連邦の行政機関（食品医薬品局）(Food and Drug Administration, FDA）によって安全性と有効性が審査される製品の1つであり，メーカーは食品医薬品局から販売承認を受けなければ国内で製品を流通させることができない．医療機器と医薬品については，まず食品医薬品局が製品に不合理な危険性がないと判断しているのである．

医療機器と医薬品が他の一般的な製品と最も異なるのは，メーカーだけでは

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10) 欠陥（defects）とは，簡単にいえば製品に内在する不合理な危険を意味し，製造上の欠陥（manufacturing defects），設計上の欠陥（design defects），そして警告上の欠陥（information or warning defects）の3つからなる． See, e.g., David G. Owen, The Evolution of Products Liability Law, 26 Rev. Litig. 955, 983-84 (2007).

なく医師が患者の安全のために大きな役割を果たしている点である．自動車などのように連邦法の規制を受けている製品は他にもあるものの，専門家である医師が最終消費者の保護のために関与する製品は他にない．では，医師が関与していることの意味は何か．

医療機器と医薬品（処方薬）については，メーカーの義務が他の一般的な製品とは異なる．すなわち，他の製品ならばメーカーが最終消費者に対して直接負うはずの義務の一部が医師に対して負う義務として構成され，その代わりに医師が最終消費者である患者に義務を負う．具体的にいえば，メーカーは製品の危険性を医師に対して十分に警告しなければならず，医師はその警告を前提にして，患者のために合理的な注意を払って治療（医薬品を処方，または，医療機器を使用）することになる11)．これは，「知識ある媒介者の法理」（learned intermediary doctrine）と呼ばれる．専門的な知識を持つ医師でなければ，個別の患者にとっての製品のリスクと便益を判断することが難しいため，メーカーは医師に十分な情報を提供する義務を負い，患者に直接警告する義務を負わないのである．

3　医療機器に関する製造物責任

医療機器に関する製造物責任は，部材メーカーに対するものと医療機器メーカーに対するものがある．以下，それぞれについて順に分析する．結論からいえば，医療機器に関する製造物責任は，連邦の制定法と判例法によって一部制限されている．

3.1　部材メーカーに対する製造物責任

医療機器メーカーに対する部材供給を円滑にするために，アメリカでは州の判例法である製造物責任法と連邦の法律がそれぞれ機能している．具体的にい

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11) See, e.g., David G. Owen, Product Liability Law 630-33 (2d ed. 2008).　See also Michael J. Summerhill & Aaron M. Chandler, Company Representatives in the Operating & Treatment Room: How to Navigate the Ever-Expanding Theories or Liability for Medical Device & Pharmaceutical Companie, 12 DePaul J. Health Care L. 253 (2009); Richard B. Goetz & Karen R. Growdon, A Defense of the Learned Intermediary Doctrine 63 Food Drug Law J. 421 (2008)．なお，知識ある媒介者の法理が適用されない例外としてよく知られているのは，大規模な予防接種とピルの処方の2つである．

えば，部材メーカーの責任は限定されている．その点について，欧州とわが国は同じ態度をとっている．例えば，欧州では製造物責任に関連するEC指令に部材メーカーの責任を限定する旨の定めがあり[12]，加盟国の製造物責任法に同様の定めが設けられている[13]．また，実は日本の製造物責任法にも，部材メーカーの免責事由を定めている条文（第4条2号）がある[14]．

アメリカでは，州の判例法によって部材メーカーの責任が限定されている．先に説明したとおり，アメリカには州法と連邦法の2つの法があるものの，製造物責任法は主に州の判例法からなる．そして，欠陥のない部材を供給した業者は，一般的には製造物責任を負わない[15]．また，医療機器の製造にあたっては，部材メーカーと医療機器メーカーの協力を支援する州の判例法が確立している．すなわち，部材メーカーは欠陥のない部材を医療機器メーカーに提供し，医療機器の製造に実質的に関与していない場合には責任を負わないが，部材と最終製品の組み合わせから生じる不合理な危険を認識している場合には，少なくとも医療機器メーカーに警告する義務を負う[16]．

このように，合理的なほど十分に安全な部材を供給している業者は製造物責

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12) Art. 7 of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJL 210, 07/08/1985, P. 29.　ちなみに，2006年に公表された最新のEC委員会報告書によれば，部材メーカーの免責については問題として認識されていない．Commission of the EC, Third Report on the application of Directive 85/374/EEC concerning liability for defective products (2006).

13) イングランドの製造物責任法については，Consumer protection Act, 1987, c. 43, § 3 (Eng.)．なお，データベースを筆者が検索したところ，イングランドにおいて医療機器関連で部材メーカーが提訴された判例は見当たらない．製造物責任に関する判例は，50件ヒットする（サマリー部分に"product liability"を含む事件）（2009年12月4日時点）．しかしながら，医療機器（medical device or product）に関する事件と部材メーカーに関する事件は，まったくヒットしない．唯一のブレスト・インプラントの判例では部材メーカーが提訴されておらず，提訴されたインプラント製造業者（Biosil Limited）が勝訴している．裁判所は，原告が立証責任を果たしていないことを理由に訴えを棄却した．Foster v Biosil (2001) 59 B.M.L.R. 178.

14) 製造物責任法（平成6年7月1日法律第85号）第4条2号を参照．「前条の場合において，製造業者等は，次の各号に掲げる事項を証明したときは，同条に規定する賠償の責めに任じない．当該製造物が他の製造物の部品又は原材料として使用された場合において，その欠陥が専ら当該他の製造物の製造業者が行った設計に関する指示に従ったことにより生じ，かつ，その欠陥が生じたことにつき過失がないこと．」．

15) See, e.g., David G. Owen, Product Liability Law § 15.3 (2d ed. 2008).

16) See, e.g., American Law of Products Liability §§ 8:10 and 8:12 (Timothy E. Travers ed. 3d)..

任を負うことがなく，部材を組み合わせた最終製品の不合理な危険性について認識している場合には，部材メーカーは医療機器メーカーに十分に警告して部材を供給すればよい，というのが判例法の支配的な見解である．

3.1.1　データベースを利用した調査

欠陥のない部材を供給した業者が責任を負う場合は，極めて少ない．データベースを使って筆者が調査を行ったところ，部材メーカーが自らの製品に欠陥がない場合に不利な判決を受ける可能性は，約5パーセントにとどまる17)．しかも，医療機器の製造に関連して部材メーカーが敗訴した事例は1件も見当たらない18)．要するに，部材メーカー，とりわけ医療機器に関連して部材を供給した業者が製造物責任を負う場合は稀だ，ということである19)．

3.1.2　責任が限定されている理由

なぜ，部材メーカーの製造物責任は限定されているのか．その理由は，部材メーカーが最終製品の危険性を除去する能力に比較的乏しいことにある20)．

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17) ウェストロー（Westlaw）のカスタム・ダイジェスト（custom digest）を利用した調査の結果．キーナンバー（313 AK 174）は，"components and raw materials" に関連する判例のダイジェストに対応している．そして，検索でヒットする判例数は，州裁判所が84件，連邦裁判所が65件の計149件（ヘッドノートの数は，州裁判所が139件，連邦裁判所が88件の計227件）である．そして，州裁判所の判例のうち，部材自体に欠陥がない場合に部材メーカーに不利な判決（被告勝訴の略式判決の破棄等）が下されたのは3件である（2010年3月12日時点）．

18) 州裁判所の判例については，Artiglio v. General Electric Co., 71 Cal. Rptr. 2d 817 (Cal. App. 1998)；In re New York State Silicone Breast Implant Litigation, 642 N.Y.S.2d 681 (N.Y.A.D. 1 Dept. 1996)；Parker v. E.I. DuPont de Nemours & Co., Inc., 909 P.2d 1 (N.M. App. 1995)；Matter of New York State Silicone Breast Implant Litigation, 632 N.Y.S.2d 953 (N.Y. Sup. 1995)；Hoyt v. Vitek, Inc., 894 P.2d 1225 (Or. App. 1995)；Bond v. E.I. DuPont De Nemours and Co., 868 P.2d 1114 (Colo. App. 1993)．連邦裁判所の判例については，In re Temporomandibular Joint (TMJ) Implants Products Liability Litigation, 97 F.3d 1050 (8th Cir. 1996) (Minn.)；In re TMJ Implants Products Liability Litigation, 872 F. Supp. 1019 (D. Minn. 1995)；Jacobs v. E.I. DuPont de Nemours & Co., 67 F.3d 1219 (6th Cir. 1995) (Tenn.)；LaMontagne v. E.I. DuPont De Nemours & Co., Inc., 41 F.3d 846 (2d Cir. 1994)；Apperson v. E.I. DuPont de Nemours & Co., 41 F.3d 1103 (7th Cir. 1994) (Ill.)；Kealoha v. E.I. DuPont de Nemours & Co., 844 F. Supp. 590 (D. Hawaii 1994)；Nowak v. E.I. DuPont De Nemours & Co., Inc., 827 F. Supp. 1334 (W.D. Mich. 1993)；Anguiano v. E.I. DuPont de Nemours and Co., Inc., 808 F. Supp. 719 (D. Ariz. 1992)；Miller v. E.I. DuPont de Nemours and Co., 811 F. Supp. 1286 (E.D. Tenn. 1992)．

19) 少なくとも筆者の調査によれば，医療機器に関連して提訴されたのはブレスト・インプラントと人工骨の部材メーカーに限られており，すべての事件で被告の部材メーカー側が勝訴している．